The OrthoMedix Group, Inc.

MEMORANDUM

Date: June 9, 2015
To: GlobalMed / Osteomed Implantes
From: J.D. Webb
Subject: DPZ Pedicle Screw System 510k (K150294)

The DPZ Pedicle Screw System has been cleared for marketing by the FDA. The attached list shows the catalogue numbers that were included in this submission. It is important that the exact verbiage of the attached indications are used in all marketing materials and that the attached label and package insert be implemented for the U.S.

I appreciate the opportunity to have aided you in gaining FDA clearance to market your device and look forward to future products that I can help you with.

Sincerely

JD Webb

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Approved Components

IMPLANTS

Reference No.	Description
117-250-030 - 117-250-055	DPZ PEDICULAR SCREW – MOVING HEAD Ø5,0 X 30-55 mm
117-260-030 - 117-260-055	DPZ PEDICULAR SCREW – MOVING HEAD Ø6,0 X 30-55 mm
117-270-030 - 117-270-055	DPZ PEDICULAR SCREW – MOVING HEAD Ø7,0 X 30-55 mm
117-280-030 - 117-280-055	DPZ PEDICULAR SCREW – MOVING HEAD Ø8,0 X 30-55 mm
117-140-025 - 117-140-040	DPZ PEDICULAR SCREW – FIXED HEAD Ø4,0 X 25-40 mm
117-150-030 - 117-150-055	DPZ PEDICULAR SCREW – FIXED HEAD Ø5,0 X 30-55 mm
117-160-030 - 117-160-060	DPZ PEDICULAR SCREW – FIXED HEAD Ø6,0 X 30-60 mm
117-170-030 - 117-170-055	DPZ PEDICULAR SCREW – FIXED HEAD Ø7,0 X 30-55 mm
117-180-035 - 117-180-055	DPZ PEDICULAR SCREW – FIXED HEAD Ø8,0 X 35-55 mm
117-150-035 - 117-150-055	DPZ PEDICULAR SCREW – LONG HEAD Ø5,0 X 35-55 mm
117-160-040 - 117-160-055	DPZ PEDICULAR SCREW – LONG HEAD Ø6,0 X 40-55 mm
117-170-040 - 117-170-055	DPZ PEDICULAR SCREW – LONG HEAD Ø7,0 X 40-55 mm
117-180-040 - 117-180-055	DPZ PEDICULAR SCREW – LONG HEAD Ø8,0 X 40-55 mm
113-010	DPZ PEDICULAR LOCKING DEVICE (SET SCREW)
115-002-035 - 115-002-075	DPZ PEDICULAR BAR DTT 35-75 mm
121-005	DPZ PEDICULAR HOOK DTT
121	DPZ PEDICULAR SCREW DTT

115-001-035 - 115-001-500	DPZ PEDICULAR UNION ROD 35-500 mm
INSTRUMENTS	
010-001	Round head needle
010-002	Triangular head needle
010-017	Guide wire for measuring
010-020/21	Rigid tapping 5,0/6,0 mm
010-022	Screw length measuring
010-023	Rod bending pliers
010-024	Cortical driller
010-025/26	Scaled driller 5,0/6,0 mm
010-029	Holder for rod
010-030	Holder for DTT bar and hook
010-032	DTT hook positioner
30.009.00020/22	Injected instrument tray
30.018.00062	Open anti-torque wrench
30.018.00068	Bar impactor
30.018.00069	Interchangeable T-handle
30.018.00084	Compressor
30.018.00085	Distractor
30.018.00095	Screwdriver for DTT Screw
30.018.00096	Feeler
30.018.00098	Bar positioner hook type
30.018.00102	T-30 Hexalobular Screwdriver
30.042.00002	Introductory screwdriver for fixed head screw
30.042.00003	Introductory screwdriver for moving head screw
30.042.00004	Tweezer for DPZ II Torx T-30 Locking Device
30.042.00005	DPZ II Torque Wrench
30.043.00002	Rod persuader
610-004	Anti-torque wrench
610-029	Long head screw thread breaker
610-042	Hammer

Approved Indications

The DPZ Pedicular Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

The DPZ Pedicular Fixation System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis; and failed previous fusion.

Sample Label

OSTEOMED
INDÚSTRIA BRASILEIRA

Rx

ESX Medical Innovation
9900 West Sample Road, Suite 300
Coral Springs, FL 33076
954-825-0400

EC REP

OBELIS S.A
BD. GÉNÉRAL WAHIS, 53
1030 BRUSSELS, BELGIUM

CE 1023

NOME COMERCIAL: COMMERCIAL NAME **SISTEMA DE FIXAÇÃO PEDICULAR DPZ**
DPZ PEDICULAR FIXATION SYSTEM

COMPONENTE: COMPONENT: **PARAFUSO PEDICULAR DPZ CABEÇA FIXA Ø4,0 x 25MM**
DPZ PEDICULAR SCREW - FIXED HEAD Ø4,0 x 25MM

LOT XXXXXXX
LOTE/ BATCH CODE

OF/PO: XXXXXXX

QUANTIDADE: 1 KIT
QUANTITY

REF Xx.xxx.xxxxx
CÓDIGO/ CATALOG NUMBER

MAT. PRIMA: XXXXXXXXXXXXX
MATERIAL

REGISTRO ANVISA Nº: XXXXXXXXX
ANVISA REGISTER

NÃO ESTERIL
NON STERILE

ESTERILIZAR ANTES DO USO
STERILIZED BEFORE USE

PRODUTO DE USO ÚNICO - PROIBIDO REPROCESSAR
SINGLE USE PRODUCT **FORBIDDEN REPROCESS**

NOME TÉCNICO:
TECHNICAL NAME

SPECIFICATIONS, TECHNICAL CHARACTERISTICS, DESCRIPTION OF THE PRODUCT, INDICATION, CONTRA-INDICATION, HANDLING, PRECAUTIONS, RESTRICTIONS, WARNINGS, PRECAUTIONS, STERILIZATION, PACKAGING, STORAGE AND TRANSPORTATION: **SEE INSTRUCTIONS FOR USE**

FABRICANTE
MANUFACTURER

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JARDIM ANHANGUERA - CONDOMINIO INDUSTRIAL CONPARK
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ENGENHEIRO RESPONSÁVEL/ ENGINEER IN CHARGE:
FERNANDO ARGENTON NETO CREA/SP - 060.500.532-4
AUTORIZAÇÃO DE FUNCIONAMENTO/ OPERATIONAL LICENSE: 800.719-1

	CUIDADO	CAUTION
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE
NON STERILE	NÃO ESTERIL	NON STERILE PRODUCT
	NÃO USAR SE A EMBALAGEM ESTIVER DANIFICADA	DON'T USE IF PACKAGE IS DAMAGED
	PROTEGER DA LUZ SOLAR	KEEP AWAY FROM SUNLIGHT
	PROTEGER DA ÁGUA	KEEP AWAY FROM WATER
15 °C – 40 °C	ARMAZENAR EMTEMPERATURA CONTROLADA (15-40°C)	STORAGE AT CONTROLLED TEMPERATURE (15-40° C)
25% – 60%	ARMAZENAMENTO LIMITE DE UMIDADE (25%-60%)	STORAGE HUMIDITY LIMITATION (25%-60%)
	NÃO REUTILIZAR	DO NOTREUSE

Xxxx-xx
FABRICAÇÃO
MANUFACTURE DATE

20XX-YY
VALIDADE/ USE BY

12345678

INDÚSTRIA E COMÉRCIO DE IMPLANTES

INSTRUCTION FOR USE

DPZ Pedicular Fixation System

CAUTION: USA law restricts this device to sale by or on the order of physician.

IMPORTANT NOTE TO OPERATING SURGEON

The DPZ Pedicular Fixation System was developed to promote the fixation and stabilization of vertebral spine, however, built only to assist the bone regeneration and not to substitute the structures of human skeleton. To provide biomechanical stability, the implants provide a natural way to the regeneration of bone tissues. The system is implanted by posterior way.

As the posterior structure of column work physiologically in compression, the DPZ Pedicular Fixation System is an implant for resist the force of compression. The best place to posterior anchor is the pedicular region.

The implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.

The surgical treatment has been used for traumatic injuries of the spine. This approach, more aggressive, ensures immediate stability restoration of the injured segment, allowing early rehabilitation programs, making easier the nursing care and minimizing possible complications resulting from immobility of the patients.

The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

DESCRIPTION

DPZ PEDICULAR FIXATION SYSTEM

The DPZ Pedicular Fixation System is a set of metallic implants (medical devices) complementary and compatible between them, anatomic and developed to be used in spine surgery, to provide stabilization, fixation and correction of the sacral, lumbar and thoracic segments of the spine.

The products are an open system, where all the medical devices are supplied and sold individually.

The surface finishing of the medical devices is obtained from mechanical polishing and anodic passivation.

The DPZ Pedicular Fixation System consists of longitudinal rods, monoaxial screws, polyaxial screws, and transverse connectors. It is manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and CP titanium conforming to ASTM F67.

FUNDAMENTALS OF OPERATION AND ACTION

The DPZ Pedicular Fixation System was developed to promote the fixation and stabilization of the vertebral spine, however, built only to assist the bone regeneration and not to substitute the structures of human skeleton.

To provide biomechanical stability, the implants provide a natural way to the regeneration of bone tissues.

The system is implanted by a posterior approach.

As the posterior structure of column works physiologically in compression, the DPZ Pedicular Fixation System is an implant for resisting the force of compression. The best place for posterior anchor is the pedicular region.

The surgical treatment is used for traumatic injuries of the spine. This approach, more aggressive, encourages immediate stability and restoration of the injured segment, allowing early rehabilitation programs, making easier the nursing care and minimizing possible complications resulting from immobility of the patient.

SELECTION CRITERIA

The correct choice of the shape, size and design of the implantable device for each patient is essential for surgical success. The surgeon is responsible for choosing the implants, and this depends of each patient. The excess weight of the patient can be responsible for forces and deformation over the implants that can accelerate material fatigue and/or can produce deformation or failure of the implants.

The size and shape of bone structure determine the size, the form and the type of implant. Once implanted, they will be exposed to loads and deformation. Those loads applied repeatedly should be considered by the surgeon when choosing the implant, its implantation and during the follow-up post-surgery. The action of these loads could cause fatigue of the implant, leading to rupture of the material before the bone graft is totally consolidated.

INDICATIONS

The DPZ Pedicular Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

The DPZ Pedicular Fixation System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis; and failed previous fusion.

CLEANING AND DECONTAMINATION:

Instruments are supplied clean and NOT STERILE, and must be sterilized prior to use.

Conditions for Use

All instruments must first be cleaned before sterilization and introduction into a sterile surgical field.

Preparation for Cleaning

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. An enzymatic cleaner bath (soak) or a solution of water and neutral pH detergent are effective in removing organic material from instruments. Use distilled water if possible. Instruments should be fully submerged for at least ten (10) minutes.

Cleaning

- Instruments must be thoroughly cleaned. Be sure dissimilar metal instruments are separated.
- Confirm that all cannulated and modular instruments are fully disassembled. Ensure that all cannulas are flushed until cleaning solution runs clear and that all instruments are completely immersed.
- Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments.
- Once instruments are cleaned and disassembled, place instruments in an ultrasonic cleaner with warm enzymatic detergent for a minimum of fifteen (15) minutes. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean.
- Rinse instruments under running water for at least one (1) minute to remove solutions.
- Instruments should never be exposed to cleaning agents containing any peroxides.

Visual Inspection

Users should periodically inspect instruments for corrosion, discoloration, etc., and properly dispose of instruments that show signs of wear and tear.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

STERILIZATION

Implants and instruments of the DPZ Pedicular Fixation System are supplied clean and not sterile. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated steam sterilizer effective sterilization may be achieved using the following parameters:

Sterilization Parameters – Steam Autoclave	
Sterilizer type	Pre-vacuum
Temperature	132°C (270°F)
Sterilization time	5 minutes
Drying time	10 minutes
Condition	Wrapped

The wrap should be FDA cleared for the proposed cycle specifications

This pre-vacuum sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.

USAGE

WARNING: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

STORAGE / TRANSPORT

The storage must be in a place clean, dry and protected from solar radiation, with moderate temperature.
Do not use if package is damaged.
Be careful during transportation, avoiding shock or damage in the original package.
Keep the medical device inside the pack until use, inside the medical area.
The device must be kept in a place with temperature around 28°C, free of moisture.
In case of package or label damage, the device must be sent back to Osteomed.

PACKAGE

The implants are packaged individually in a primary package made of plastic tubes sealed by heat. The tubes are transparent, made of non toxic low density polyethylene, printed in red with the logo and the name of Osteomed. The second package is a card box, containing the primary package.
If the package or the implant is damaged, the device must be sent back to Osteomed.

VERIFYING BEFORE USE

The package and label must not show any damage and the device must have its identification printed on the device.
The device must be free of damage, without any mark or crack. The surface must be clean and polished.
The device must be handled with maximum care. The device must be removed from the package immediately before sterilization.
If the device has been dropped and is suspected to have suffered damage it must be sent back to Osteomed. However, the final judgment about the functionality of the device must be decided by the surgeon.

TRACEABILITY

All devices receive identification printed on their own bodies. This print contains information necessary to perform the traceability: trademark and batch number.
The traceability report must be kept for at least 2 years after the sale date or expiration date of the implant. Where necessary, Osteomed can require this report back at any moment without any previous notice.

PRECAUTION: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system. This is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon must be thoroughly knowledgeable, not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device. Refer to the individual system surgical technique manuals for additional important information.

A surgical technique can be obtained from the local representative or Osteomed.

DPZ Pedicular Fixation System components should not be used with components from other manufacturers. Stainless steel components may interfere with the quality of imaging obtained using MRI.

The DPZ Pedicular Fixation System has not been evaluated for safety and compatibility in the MR environment. The DPZ Pedicular Fixation System has not been tested for heating or migration in the MR environment.

During the surgical procedure, the rods may be cut to size and shaped to provide correction and maintain proper anatomic lordosis and kyphosis alignment.

After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology, for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion, the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

POSTOPERATIVE MOBILIZATION

Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

CONTRAINDICATIONS

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection or infection localized to the site of the proposed implantation is contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity (The patient must not have more than 120 kg), certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure. See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.

INFORMATION TO THE PATIENTS

The surgeon must discuss with the patient all physical and psychological limitations inherent to the use of implant, including the rehabilitation stage, physiotherapy and the use of orthopedic devices, according to medical prescription. The surgeon must warn about the risk of physical activities.
Patient with vigorous work or activities (lift weight, run, jump, or any excessive muscular work) that require a compressive resistance in the spine must be warned about the necessity of a substitution in future, to avoid the risks of fail. Smokers show a tendency of failure in the bone fusion and must be warned about this condition. Patienst with degenerative disease in advanced stage can be susceptible to a shorter life time of the fixation system so this surgical technique is faced as a palliative technique.
The Titanium and Titanium alloy are materials non ferromagnetic and don't offer any restriction about environment or equipment (X-ray, computerized axial tomography and magnetic resonance).

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely, the unsupported stress of full weight bearing.

2. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks o implant failure.

3. **MIXING METALS CAN CAUSE GALVANIC CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of galvanic corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of galvanic corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

4. **PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   - **A. The patient's weight**. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
   - **B. The patient's occupation or activity**. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
   - **C. A condition of senility, mental illness, alcoholism, or drug abuse.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
   - **D. Certain degenerative diseases**. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.
   - **E. Foreign body sensitivity.** The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
   - **F. Smoking.** Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

3. **CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING.** If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

4. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

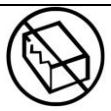
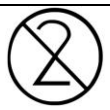
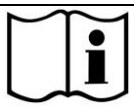
CAUTIONS IN CASE OF EXPLANTATION

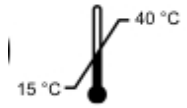
- Preserve the adjacent tissues with minimal damage to the implants.
- Radiologic monitoring.
- Clinical history of patient/implant.
- Verify the functionality of the implant before removal procedure.
- Removal registry (X-ray, computerized axial tomography).
- Microbiological study of the tissue around the implant.
- Sample of fluid and tissue for histologic exam.
- Identification of the removed implant.
- Labeling of the implant for future identification.

The discard procedure is described in the document "Product Security/Discard."

POSSIBLE ADVERSE EFFECTS

1. Bending or fracture of implant.
2. Loosening of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Infection, early or late.
5. Nonunion, delayed union.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties, including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
9. Bursitis.
10. Paralysis.
11. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
12. Death.
13. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malposition of implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
14. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
15. Damage to lymphatic vessels and/or lymphatic fluid exudation.
16. Spinal cord impingement or damage.
17. Fracture of bony structures.
18. Degenerative changes or instability in segments adjacent to fused vertebral levels.

	**Do not use if package is damaged**
	**Do not reuse**
	**Consult instructions for use**
	**Keep away from sunlight**
	**Caution**
	**Authorized representative in the European community**
	**Manufacturer**

	**Manufacture Date**
	**Use by**
	**Temperature Limitation**

POST MARKETING ASSISTANCE

OSTEOMED INDÚSTRIA E COMÉRCIO DE IMPLANTES LTDA

Washington Luis Route (SP 310), Track South , Km 172 – 6th Street W/N - Anhanguera Garden - Conpark Condominium - Rio Claro-SP-Brazil – Zip Code 13.501- 600 – Phone: (+5519) 3522-3064.
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MS 800719-1 – Registro ANVISA

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 5, 2015

Osteomed Implantes, LTDA
% Mr. J.D. Webb
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K150294
Trade/Device Name: DPZ Pedicular Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: May 4, 2015
Received: May 6, 2015

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure