Delphos Implants - Ind.Com. Importacao e Exportacao de Implantes Medicos S.A. March 29, 2019
% Mauro Malzyner
US Agent
Passarini Regulatory Affairs of America, LLC
201 S. Biscayne Blvd, Suite 1200
Miami, Florida 33131

Re: K182609
Trade/Device Name: Delphos Implants Rigid Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: February 15, 2019
Received: February 25, 2019

Dear Mauro Malzyner:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.03.29 14:59:31 -04'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182609

Device Name

Delphos Implants Rigid Fixation System

Indications for Use *(Describe)*

The Delphos Implants Rigid Fixation System is intended for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.

The Delphos Implants Rigid Fixation System implants are intended for single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	Delphos Implants Industria, Comercio, Importacao e Exportacao de Implantes Medicos S.A. Estrada Manuel Correia Lopes, Parque Empresarial Progresso, Armazem 5– Cascais – Sao Domingos de Rana - Portugal 2785-126 Telephone +351 211 955 986
Contact Person	Mauro Malzyner, Mr. US Agent Passarini Regulatory Affairs of America, LLC E-Mail: mauro@rapassarini.com.br Telephone +1 760 936 2301
Date Prepared	27/Mar/2019
Preparer / Alternate Contact	Janine Treter Regulatory Affairs Specialist Passarini Regulatory Affairs janine@rapassarini.com.br Telephone +55 47 3804 0075

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Delphos Implants Rigid Fixation System
Common Name	Bone Plate
Classification Regulations	21 CFR 872.4760, Class II
Product Code	JEY

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K080694 - Osteomed Modular Locking Fixation System - Osteomed L.P.
Reference Devices	K112457 - LeForte System Bone Plate & Screw - Jeil Medical Corporation K121589 - Biomet Microfixation Facial Plating System - Biomet Microfixation K150965 – LeForte System II - Jeil Medical Corporation K180204 - CranioMaxillofacial Fixation (CMF) System - CMF Visionare - Visionare LLC

510(k) Summary

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Date Prepared	27/Mar/2019
Preparer / Alternate Contact	Janine Treter Regulatory Affairs Specialist Passarini Regulatory Affairs janine@rapassarini.com.br Telephone +55 47 3804 0075

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INDICATIONS FOR USE

The Delphos Implants Rigid Fixation System is intended for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.

The Delphos Implants Rigid Fixation System implants are intended for single use only.

SUBJECT DEVICE DESCRIPTION

The plates are manufactured in commercially pure titanium (ASTM F67 and ISO 5832-2) and the bone screws are manufactured from titanium alloy Ti-4Al-6V ELI (ASTM F136 and ISO 5832-3) and are available on different sizes, according with the site of the implantation and the extension of the fracture.
The devices are for single use, provided non-sterile, must be properly cleaned, disinfected and sterilized before use, according the recommendations provided on the Instructions for Use provided by Delphos Implants.
The devices must only be used by qualified surgeons mastering the surgical technique, having been trained and qualified in maxillofacial surgery and/or stomatology.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have a range of plates and screws with equivalent indication for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.

Differences in the design features between the subject devices and the primary predicate device K080694 are addressed by comparison to the reference devices as listed in the tables below.

INDICATIONS FOR USE

The Delphos Implants Rigid Fixation System is intended for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.

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The devices must only be used by qualified surgeons mastering the surgical technique, having been trained and qualified in maxillofacial surgery and/or stomatology.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have a range of plates and screws with equivalent indication for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.

Differences in the design features between the subject devices and the primary predicate device K080694 are addressed by comparison to the reference devices as listed in the tables below.

Table 5.1: Substantial Equivalence on Plates

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE I	REFERENCE DEVICE II	REFERENCE DEVICE III	Substantial Equivalence Discussion
	K182609 - Delphos Implants Rigid Fixation System	**K080694 - Osteomed Modular Locking System**	**K112457 - LeForte System Bone Plate & Screw**	**K121589 - Biomet Microfixation Facial Plating System**	**K180204 - Mini and Micro Fragments Reconstruction System – CMF Visionare**	
	Delphos Implants – Ind. Com. Importação e Exportação de Implantes Médicos S.A.	**OsteoMed L. P.**	**Jeil Medical Corporation**	**Biomet Microfixation**	**Visionare LLC**	
Indication for Use	The Delphos Implants Rigid Fixation System is intended for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction. The Delphos Implants Rigid Fixation System implants are intended for single use only.	The OsteoMed Modular Locking Fixation System is intended for fracture fixation in cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction. The OsteoMed Modular Locking Fixation System implants and drills are intended for single use only.	Intended for use in Selective trauma of the mid-face, reconstruction procedures and selective orthognathic surgery of the maxilla and chin.	These devices are implantable bone plates and bone screws for facial procedures including: 1. Fractures 2. Osteotomies 3. Reconstructive procedures 4. Revision procedures where other treatments or devices have failed	CranioMaxillofacial Fixation (CMF) System - CMF Visionare is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.	**Equivalent** The subject device indication for use is identical to primary predicate device excepting for the reference to drills and the reference to the term “cranio-maxillofacial”. Drills are surgical instruments developed to assist in the installation of plates and screws and are not subject of this submission. Therefore, information on drills were suppressed from Delphos Implants indications for use Statement. In a previous submission from Delphos Implants (K172949), FDA informed that devices intended for Cranial/Neuro applications are to be reviewed by the Neurology Panel. Therefore, the words cranio-maxillofacial were replaced by maxillofacial. The subject device indication for use are within the scope of the reference devices.
Product Code	JEY	JEY	JEY, DZL	JEY, HWC	JEY, DZL	**Identical** to Primary Predicate Device and within the scope of Reference Devices.
Class	II	II	II	II	II	**Identical**

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE I	REFERENCE DEVICE II	REFERENCE DEVICE III	Substantial Equivalence Discussion
	K182609 - Delphos Implants Rigid Fixation System	**K080694 - Osteomed Modular Locking System**	**K112457 - LeForte System Bone Plate & Screw**	**K121589 - Biomet Microfixation Facial Plating System**	**K180204 - Mini and Micro Fragments Reconstruction System – CMF Visionare**	
	Delphos Implants – Ind. Com. Importação e Exportação de Implantes Médicos S.A.	**OsteoMed L. P.**	**Jeil Medical Corporation**	**Biomet Microfixation**	**Visionare LLC**	
Regulation Number	21 CFR 872.4760	21 CFR 872.4760	21 CFR 872.4760 21 CFR 872.4880	21 CFR 872.4760 21 CFR 888.3040	21 CFR 872.4760 21 CRF 872.4880	**Identical** to Primary Predicate Device and within the scope of Reference Devices.
Regulation Name	Bone Plate	Bone Plate	Bone Plate Intraosseus fixation screw or wire	Bone Plate Screw, Fixation, Bone	Bone Plate Intraosseus fixation screw or wire	**Identical** to Primary Predicate Device and within the scope of Reference Devices.
Raw material	The plates are made from commercially pure titanium (ASTM F67)	The plates are made from Titanium Alloy (ASTM F136 or commercially pure titanium (ASTM F67)	The plates are made from commercially pure titanium (ASTM F67)	The plates are made from Titanium Alloy (ASTM F136 or commercially pure titanium (ASTM F67)	The plates are made from commercially pure titanium (ASTM F67)	**Equivalent** The subject device raw materials are within the scope of the predicates raw materials.
Surface treatment	Anodization	Anodization	Anodization	Not informed	Not informed	**Identical**
Use	Single use	Single use	Single use	Single use	Single use	**Identical**
Sterilization	Non-sterile, Steam sterilization prior to use	Non-sterile, Steam sterilization prior to use	Non-sterile, Steam sterilization prior to use	Not informed	Non-sterile, Steam sterilization prior to use	**Identical**
Plates thickness	0.5, 0.6, 0.7, 0.8, 1.0, 1.3, 1.6, 2.5 mm	0.25mm ~ 2.5mm 1.0mm ~2.5mm	0.1mm, 0.2mm, 0.3mm, 0.4mm, 0.5mm, 0.6mm, 0.8mm, 1.0mm, 1.3mm, 2.5mm	Various	0.3mm, 0.7mm, 1.0mm, 1.5mm, 2.0mm, 2.54mm.	**Equivalent** The plates thickness are within the range of the predicate devices.

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE I	REFERENCE DEVICE II	REFERENCE DEVICE III	Substantial Equivalence Discussion
	K182609 - Delphos Implants Rigid Fixation System	**K080694 - Osteomed Modular Locking System**	**K112457 - LeForte System Bone Plate & Screw**	**K121589 - Biomet Microfixation Facial Plating System**	**K180204 - Mini and Micro Fragments Reconstruction System – CMF Visionare**	
	Delphos Implants – Ind. Com. Importação e Exportação de Implantes Médicos S.A.	**OsteoMed L. P.**	**Jeil Medical Corporation**	**Biomet Microfixation**	**Visionare LLC**	
Plates designs (shapes).	Orbital Type T Type Straight Type H Type X Type Z Type L Type Y Type Curved Type Rectangular Type Calvarium Plate Maxillary Type Square Type Fitting Adjustment Type Mentoplasty Type (Chin type) Double T Type BSSO Type L Adjustment Type Condylar Fracture Type	Curved Type Straight Type L Type Double Y Type X Type I Type Chin Type Mesh Type H Type Quad(Square) Type Y Type Z Type BSSO Type Orbital Type Angled Type Condyle Plate Comminution Type Strut Type Reconstruction Type	Curved Type Straight Type Square Type L Type Double Y Type X Type I Type Chin Type Calvarium Type Mesh Type H Type Hexagon Type Quad Type T Type Y Type Z Type Rigid Straight Type MG Type A Type Angled Type Angled Reconstruction Type Multi Reconstruction Type Reconstruction -Type BSSO Type	Variations of: Straight Angled Curved L-shape T-shape Z-shape X-shape Y-shapes Double Y shapes H-shape Triangle Rectangle Matrix Mesh Orbital Floor LeFort Chin	Straight Plates Rectangular Plates T Plates Y Plates Double Y Plates L Plates L 110° Plates H Plates I Plates X Plates Z Plates Orbital Plates Orbital Floor Plates Straight Locking Plates Rectangular Locking Plates Orthognathic L Plates Orthognathic Y Plates Orthognathic Canine Pillar Plates Orthognathic Zygomatic Pillar Plates Orthognathic Le Fort Plates Orthognathic Chin Plates Orthognathic Paulus Plates Orthognathic Straight Sagittal Plates Orthognathic Straight Adjustable Sagittal Plates Orthognathic Y Adjustable Sagittal Plates Orthognathic Locking Straight Sagittal Plates Orthognathic Locking Straight Adjustable Sagittal Plates Orthognathic Locking Y Adjustable Sagittal Plates	**Equivalent** Most of the plates designs are within the scope of Primary Predicate Device and Reference Devices. There are some minor differences in design types that do not introduce significantly different designs and maintain the same intended use. All the subject plates designs were evaluated through mechanical testing on worst cases representatives not raising any issue in performance.

Table 5.2: Substantial Equivalence on Screws

Trade Name Information	SUBJECT DEVICES	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE I	REFERENCE DEVICE II	Substantial Equivalence Discussion
	K182609 - Delphos Implants Rigid Fixation System	**K080694 - Osteomed Modular Locking System**	**K150965 - LeForte System II**	**K180204 - Mini and Micro Fragments Reconstruction System – CMF Visionare**	
	Delphos Implants – Ind. Com. Importação e Exportação de Implantes Médicos S.A.	**OsteoMed L. P.**	**Jeil Medical Corporation**	**Visionare LLC**	
Indication for Use	The Delphos Implants Rigid Fixation System is intended for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction. The Delphos Implants Rigid Fixation System implants are intended for single use only.	The OsteoMed Modular Locking Fixation System is intended for fracture fixation in cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction. The OsteoMed Modular Locking Fixation System implants and drills are intended for single use only.	The LeForte System II is intended for use in selective trauma of mid-face, reconstruction procedure and selective orthognathic surgery of the maxilla and chin.	CranioMaxillofacial Fixation (CMF) System - CMF Visionare is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.	**Equivalent** Most of the plates designs are within the scope of Primary Predicate Device and Reference Devices. There are some minor differences in design types that do not introduce significantly different designs and maintain the same intended use. All the subject plates designs were evaluated through mechanical testing on worst cases representatives not raising any issue in performance.
Product Code	JEY	JEY	JEY	JEY, DZL	**Identical** to Primary Predicate Device and within the scope of Reference Devices.
Class	II	II	II	II	**Identical**
Regulation Number	21 CFR 872.4760	21 CFR 872.4760	21 CFR 872.4760	21 CFR 872.4760 21 CRF 872.4880	**Identical** to Primary Predicate Device and within the scope of Reference Devices.
Regulation Name	Bone Plate	Bone Plate	Bone Plate	Bone Plate Intraosseus fixation screw or wire	**Identical** to Primary Predicate Device and within the scope of Reference Devices.
Raw material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	**Identical**
Surface treatment	Anodization	Anodization	Anodization	Not informed	**Identical**
Use	Single use	Single use	Single use	Not informed	**Identical**

Trade Name Information	SUBJECT DEVICES **K182609 - Delphos Implants Rigid Fixation System** **Delphos Implants – Ind. Com. Importação e Exportação de Implantes Médicos S.A.**	PRIMARY PREDICATE DEVICE **K080694 - Osteomed Modular Locking System** **OsteoMed L. P.**	REFERENCE DEVICE I **K150965 - LeForte System II** **Jeil Medical Corporation**	REFERENCE DEVICE II **K180204 - Mini and Micro Fragments Reconstruction System – CMF Visionare** **Visionare LLC**	Substantial Equivalence Discussion
Sterilization	Non-sterile, Steam sterilization prior to use	Non-sterile, Steam sterilization prior to use	Non-sterile, Steam sterilization prior to use	Non-sterile, Steam sterilization prior to use	**Identical**
Screw type/ diameter	Self-tapping Screw 1.2mm, 1.6mm, 2.0mm, 2.4mm, 2.7 mm Self-drilling Screw 2.0 mm Emergency Screws 1.6mm, 1.9mm, 2.3mm, 2.7 mm	Self-tapping Screw 1.2mm, 1.5mm, 1.6mm, 1.9mm, 2.0mm, 2.3mm, 2.4mm, 2.7mm Self-drilling Screw 1.2mm, 1.6mm, 2.0mm	Self-tapping Screw 1.3mm, 1.6mm, 2.0mm, 2.4mm Self-drilling Screw 1.4mm, 1.6mm, 2.0mm Emergency Screws 1.5 mm, 1.8mm, 2.3mm, 2.7mm	Self-tapping Screw 1.5mm, 2.0mm, 2.4mm, 2.7mm Self-drilling Screw 1.5mm, 2.0mm Emergency Screws 1.8mm, 2.3mm, 2.7mm	**Equivalent** The subject devices diameters are within the range of the predicate devices diameters. Performance testing were executed following worst case rationales; the subject devices are supported by mechanical testing.
Screw Length	Self-tapping Screw 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20 mm Self-drilling Screw 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 mm Emergency Screws 4, 5, 6, 7, 8, 9, 10, 12, 14mm	Self-tapping Screw 2 - 20mm Self-drilling Screw 3 - 8mm	Self-tapping Screw 2 - 20mm Self-drilling Screw 3 - 12mm	Self-tapping Screw 4-20mm Self-drilling Screw 4-11mm Emergency Screws 4-18mm	**Equivalent** The subject devices lengths are within the range of the predicate devices lengths. Performance testing were executed following worst case rationales; the subject devices are supported by mechanical testing

The subject device plates are substantially equivalent to the primary predicate device K080964, or reference devices K112457, K121589 and K180204, in designs and range of dimensions. The reference devices K112457 is for substantial equivalence of the designs not encompassed by the primary predicate that are the Calvarium Type and T Type. The reference device K121589 is for substantial equivalence for the Rectangle plates. The reference device K180204 is for substantial equivalence for the Maxillary Plates (Orthognathic plates).

The subject plates thickness is substantially equivalent to the primary predicate and reference devices since fall in its range of thickness.

The subject device screws are substantially equivalent to the primary predicate device K080964, or reference devices K150965 and K180204, in designs and range of dimensions. The reference devices K150965 is for substantial equivalence of the Emergency Screws diameters and the reference device K180204 is for substantial equivalence of the Emergency Screws lengths.

The following performance data supports the substantial equivalence determination:

The plates are manufactured in commercially pure titanium conforming to ASTM F67 and ISO 5832-2. The plates types of titanium are the same to that used for fabrication of the predicate devices cleared under K080694, K112457, K121589 and K180204.

The screws are made of titanium alloy according to the requirements of ASTM F136 and ISO 5832-3. The screws alloy are the same to that used for fabrication of the predicate devices cleared under K080694, K150965 and K180204.

Biocompatibility of the subject device materials was supported by cytotoxicity, irritation and skin sensitization, and acute systemic toxicity testing according to according to ISO 10993-5, ISO 10993-10 and ISO 10993-11, respectively.

The performance of the subject devices are demonstrated through mechanical testing of plates and screws according to ASTM F382 and ASTM F 543.

For the plates the critical points, flexural stiffness, elastic limit stress, bending moment, and structural stiffness was determined based on the requirements of ASTM F 382 - Bending test in 4 static points. It was also performed the Fatigue Test (Plate Fold) due to the need for conformation by the users. For the screws, torsion, screwing/unscrewing, pullout and screw thread testing were executed.

The tested subject devices exhibit a level of performance equivalent to that reviewed for the predicate devices. No clinical data were included in this submission.

The subject devices are provided non-sterile and have no expiration date defined. Steam sterilization validation was performed according to ISO 17665-1.

CONCLUSION

The documentation submitted in this premarket notification demonstrates that the subject devices have comparable features and performance and, therefore, are substantially equivalent to the identified predicate devices.