



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

September 21, 2015

Osteomed
Piedad Pena
Regulatory Affairs Manager
3885 Arapaho Rd
Addison, Texas 75001

Re: K151195
Trade/Device Name: Osteomed Imf Screw
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: September 4, 2015
Received: September 10, 2015

Dear Piedad Pena:

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,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. A faint, semi-transparent watermark of the letters "FDA" is visible behind the signature.

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K151195

Device Name: OsteoMed ICON IMF Screw System

Indications for Use:

The OsteoMed ICON IMF Screw System is intended and indicated for the temporary ligature and wire lock fixation for temporary constriction and stabilization of fracture bone segments in the oral cavity in conjunction with primary fixation devices.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



K151195

510(k) SUMMARY

OsteoMed ICON IMF Screw System

Name of Submitter: OsteoMed
3885 Arapaho Road
Addison, TX 75001
972 677 4600
972 677 4601 (fax)

Contact Person: Mrs. Piedad Pena, M.S.

Date Prepared: September 4, 2015

Device Proprietary Name: OsteoMed ICON IMF Screw System
Device Common Name: IMF Fixation Screw and wire
Classification Name: 21CFR 872.4880: Intraosseous fixation screw or wire
Product Code: DZL

Primary Predicate:

OsteoMed QUICK-FIX, K962774

Classification Name: 21CFR 872.4880: Intraosseous fixation screw or wire; Product Code: DZL; Class: II

Reference Predicate:

Auto-Drive Bone Screw System, K974785

Classification Name: 21CFR 888.3040, Smooth or threaded metallic fixation fastener, Product Code HWC, Device Class: II

Summary:

Device Description:

The OsteoMed ICON IMF (Intermaxillary Fixation) Screw System is offered in 2.4mm and 2.0mm standard IMF screws in lengths from 10mm to 20mm (thread lengths from 5mm to 15mm) and 2.0mm ICON AutoDrive IMF Screws in lengths from 12mm to 18mm (thread lengths of 8mm to 14mm).

The implants of the OsteoMed ICON IMF Screw System are made from Titanium alloy (ASTM F-136) and the ligature wire is made from Stainless Steel.

The system instruments include drill bits, wire cutters, pliers, drill guides and screwdrivers to facilitate the placement of screws and ligature wires. The instrumentation is made from various grades of stainless steel, anodized aluminum, and/medical grade polymer.

Intended Use/Indications for Use:

The OsteoMed ICON IMF Screws System is intended and indicated for the temporary ligature and wire lock fixation for temporary constriction and stabilization of fractured bone segments in the oral cavity in conjunction with primary fixation devices.

OsteoMed
3885 Arapaho Road
Addison, Texas 75001
(973) 677-4600 FAX: (800) 390-2620
Customer Service: (800) 456-7779



Summary of Technological Characteristics:

Table 1: Technology Comparison to the Primary Predicate and Reference Device

System / Device Name/510(k)/ Purpose	<i>OSTEOMED ICON IMF Screw System (New)</i>	<i>OSTEOMED Quick-fix System K962774</i> Primary Predicate	<i>OsteoMed Auto-Drive Bone Screw K974785</i> (Reference Predicate) <i>self-driving tip features</i>
Classification	Class II 21 CFR 872.4880 DZL	Class II 21 CFR 872.4880 DZL	Class II 21 CFR 888.3040 HWC
Device Name Classification:	Intraosseous fixation screw or wire. a) Identification. An intraosseous fixation screw or wire is a metal device intended to be inserted into fractured jaw bone segments to prevent their movement.	Intraosseous fixation screw or wire. a) Identification. An intraosseous fixation screw or wire is a metal device intended to be inserted into fractured jaw bone segments to prevent their movement.	Smooth or threaded metallic bone fixation fastener.
Indication for Use/Intended Use	The device is intended and indicated for the temporary ligature and wire lock fixation for temporary constriction and stabilization of fracture bone segments in the oral cavity in conjunction with primary fixation devices.	The device is intended and indicated for the temporary ligature and wire lock fixation for temporary constriction and stabilization of fracture bone segments in the oral cavity in conjunction with primary fixation devices.	Fixation secondary to trauma or reconstruction of the craniofacial and maxillofacial skeleton and bones of the hand
Technology	The screws fixate on bone in conjunction with ligature wire to allow fixation and stabilization of the fracture.	The screws fixate on bone in conjunction with ligature wire to allow fixation and stabilization of the fracture.	The screws fixate on bone in conjunction with plates for rigid fixation. (N/A, this device does not use plates)
Screw Driving technology for implantation	The standard screws are implanted after a pilot hole has been created in the desired location. AutoDrive screws do not require pilot hole for implantation, they are self-drilling screws.	The standard screws are implanted after a pilot hole has been created in the desired location.	AutoDrive screws do not require pilot hole for implantation, they are self-drilling screws.
Screw Material	Ti6Al4V per ASTM F136	Ti6Al4V per ASTM F136	Ti6Al4V per ASTM F136
Principles of Operation	Rigid Fixation and Wire Lock stabilization	Rigid Fixation and Wire Lock stabilization	Rigid Fixation

System / Device Name/510(k)/ Purpose	<i>OSTEOMED ICON IMF Screw System (New)</i>	<i>OSTEOMED Quick-fix System K962774</i> Primary Predicate	<i>OsteoMed Auto-Drive Bone Screw K974785</i> (Reference Predicate) <i>self-driving tip features</i>
Screw (type and length range according to screw diameter)	2.4mm IMF Screw (standard) Length range: 10mm-20mm Thread range: 5mm to 15mm (Same as Primary Predicate; cleared K962774) 2.0mm IMF Screw (standard) Length range: 10mm-20mm Thread range: 5mm to 15mm 2.0mm IMF AutoDrive Screw Length range: 12mm-18mm Thread range: 8mm-14mm	2.4mm IMF Standard Screw Length range: 10mm-20mm Thread range: 5mm to 15mm (Cleared)	2.0mm AutoDrive Screw Length range: 4mm-8mm Thread range: 3mm-7mm (Cleared)
Instrumentation (Materials)	<ul style="list-style-type: none"> • Stainless Steel • Anodized aluminum • Medical grade polymer 	<ul style="list-style-type: none"> • Stainless Steel • Anodized aluminum • Medical grade polymer 	<ul style="list-style-type: none"> • Stainless Steel • Anodized aluminum • Medical grade polymer
Instrumentation	drill bits, wire cutters, pliers, drill guides and screwdrivers to facilitate the placement of screws and ligature wire	drill bits, wire cutters, pliers, drill guides and screwdrivers to facilitate the placement of screws and ligature wire	screwdrivers to facilitate the placement of screws
Sterilization	Packaged and sold Non-sterile, requires sterilization prior to use	Packaged and sold Non-sterile, requires sterilization prior to use	Packaged and sold Non-sterile, requires sterilization prior to use
Biocompatibility	Ti alloy per ASTM F136 is a biocompatible material	Ti alloy per ASTM F136 is a biocompatible material	Ti alloy per ASTM F136 is a biocompatible material

Substantial Equivalence Discussion:

The OSTEOMED 2.0mm ICON Standard IMF Screw and the 2.0mm ICON AutoDrive IMF Screw are the same as the predicate device (2.4mm QuickFix MMF Screw, K962774) in the following ways:

- The screws have the same Regulatory Classification (21 CFR 872.4880 DZL)
- The screws have the same indication for use.
- The technology and features of the screws are the same (screws to fixate and allow ligature with wire)
- The range of the screw length is the same as, or encompassed by, that of the predicate:
 - Overall Length = 10mm - 20mm
 - Thread Length = 5mm - 15mm
- The length of the screw head, the head diameter, and cross-sectional areas through the wire holes are the same as the predicate device.
- The 2.0mm ICON Standard IMF Screw has the same number of wire fixation holes (1) as the predicate

- The screws are manufactured from the same materials (Titanium alloy per ASTM F136) as the predicate and therefore have the same biocompatibility.
- The instrumentation and materials used in conjunction with these screws are the same
- The screws are packaged and sterilized in the same manner and same parameters as the predicate device.

Differences between the new devices and the predicate, do not affect safety and effectiveness

- The 2.0mm ICON AutoDrive IMF Screw has more wire fixation holes (2) than the predicate (1)
- The 2.0mm ICON Standard IMF Screw has a smaller cross-sectional area through the wire fixation holes (1.43 mm²) than the predicate (2.04 mm²)
- The 2.0mm ICON AutoDrive IMF Screw has a different tip (sharp, pointed, single thread-cutting flute) than the predicate (blunt, rounded) but was equivalent to the reference predicate.

The performance testing comparison listed below showed the new devices were equivalent and did not raise new safety and effectiveness issues.

Performance/Clinical Data:

The OsteoMed ICON IMF Screws (2.0mm Standard IMF screws and the 2.0mm AutoDrive IMF screws) were compared to the OsteoMed QuickFix 2.4mm standard MMF Screws (K962774-primary predicate) and the 2.0mm AutoDrive Screws (K974785-reference predicate). The 2.0mm AutoDrive IMF screws and the 2.0mm standard IMF screws underwent verification testing to ensure that the design features meet the required mechanical strength criteria for their intended use compared to the predicate device. The intended use of the OsteoMed ICON IMF Screw System is the same as OsteoMed 2.4mm QuickFix screw system (K962774).

The performance testing included failure torque testing of the new devices and the predicate devices in accordance with ASTM F543. All devices met the minimum failure torque requirement based on screw diameter according to the standard. Also, insertion torque testing in accordance with ASTM F543 was performed for all devices. All devices met the required failure torque to insertion torque (FT/IT) ratio of FT/IT > 1.0 according to the standard. Lastly, pull-out force and bending force testing was performed on the new devices using equivalent methods to those shown in the primary predicate 510k K962774 and compared against the predicate device results in K962774. The performance testing showed that the new devices were equivalent to the predicate device. Simulated use was performed as part of validation for the new screws and were found to be equivalent to the predicate device.

Biocompatibility and Sterilization testing was justified to the already tested predicate device. No changes to materials, packaging, or sterilization were made, therefore the new devices are equivalent to the predicate device.

OsteoMed believes that these non-clinical tests have demonstrated that these devices are safe and effective as the predicate device; therefore, clinical testing is not required to support substantial equivalence.

Substantial Equivalence:

The substantial equivalence of the OsteoMed ICON IMF Screw System is based on similarities in intended use, indications for use, material, function, technology, performance, design, sterilization, and operational principles to the OsteoMed QuickFix (K962774, primary predicate) and design, material and operating principles as the AutoDrive self-drilling features for the OsteoMed AutoDrive Bone Screw (K974785) reference predicate.

Conclusion:

Substantial equivalence was shown through failure torque testing, insertion torque testing, pull-out force testing, and bending testing when compared to known standards and to the predicate devices. The indications, design, technology and operational principles are similar between the subject devices and primary predicate OsteoMed 2.4mm QuickFix MMF Screw (K962774), and reference predicate OsteoMed 2.0mm AutoDrive Screw (K974785), therefore OsteoMed believes that the OSTEOMED 2.0mm ICON Standard IMF Screw and OSTEOMED 2.0mm ICON AutoDrive IMF Screw do not raise any new safety or effectiveness issues.

The assessment of the non-clinical data demonstrated the devices were as safe and effective as the predicate devices OsteoMed QuickFix (K962774) and AutoDrive Bone Screw (K974785). In conclusion, the OsteoMed IMF Screw System have been evaluated and proven to be substantially equivalent to the predicate device.