

510(k) SUMMARY
(as required by 807.92(c))

K110275

JUN - 3 2011

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Tanya O'Brien
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Submitter of 510(k): Bernhard Forster GmbH
Westliche Karl-Fredrichstrasse 151
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Date of Summary: January 18, 2011

Trade/Proprietary Name: Ortho Easy Pin

Classification Name: Implant, endosseous

Product Code: OAT

Intended Use: The device is intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only.

Device Description: The Ortho Easy Pin is designed for use in orthodontic treatments as element of anchorage. The screws are made of titanium alloy. The slots in the screw head are cross-shaped. Rectangular wires are inserted to accommodate orthodontic elements, such as arches, elastic bands and brackets. Preferably, the wire should be fixed to the screw head using an elastic band or steel ligature. A retention groove below the slots serves as the anchor for fixing elements in the slot. The thread of the Pin is self-trapping and self-drilling. The Pin is inserted and screwed into the bone either manually

or mechanically. To insert the screw, the hexagon head of the screw is picked up using an instrument. The sleeve between the thread and the functional head serves to protect the soft tissue. These screws are supplied non-sterile. Therefore, the device must be sterilized prior to use. Steam sterilization is recommended. The device is available in different lengths (6, 8, 10, 12 mm), diameter 1,7 mm, and supplied in sealed polyethylene bags.

Predicate Device:

Tomas PIN (K062733), Dentaurum; Dual Top Anchor System Screws (K033767), Jeil Medical Corporation

Substantial Equivalence:

All reports show that the Ortho Easy Pin is equivalent to devices currently on the market. They are made of the same material and have similar dimensions and characteristics. Potential adverse effects are identical to those of predicate devices. This device is manufactured from titanium ASTM-F 136-98 which is generally used in this kind of bone screw. Similar grade 5 titanium alloy devices are manufactured and sold around the world. This device is substantially equivalent in design, material, intended use and function to the products listed as predicate devices.

Performance Testing

Testing was done to determine the torque levels, forces and insertion lengths while inserting OrthoEasy® pin. The level of torque is comparable to predicate devices (tomas®-pin, Dual-Top Anchor Screw) which were investigated with the measurement equipment under the same parameter. Testing was also done to determine the effect of impact on tooth roots. This testing found the risk of root damage while inserting an OrthoEasy® pin into a root is not justified as the thread peak is not able to cut the tooth. In conclusion it can be said that the thread peak of the OrthoEasy® pin has a protective function.

Conclusion

The OrthoEasy® pin features a low insertion level at the beginning. Due to the design parameters, the torque increases at the end of the insertion process. This provides feedback to the doctor during the

insertion process. The amount of torque is clearly far from the load limit of 30 Ncm. No fracture occurred during our measurements. The measurement results that the OrthoEasy® pin withstands the active forces during an orthodontic treatment. The level of torque is comparable to predicate devices (tomas®-pin, Dual-Top Anchor Screw) which were investigated with the measurement equipment under the same parameter. Therefore it is to estimated OrthoEasy® pin will show the same clinical results like the other screws.

Substantial Equivalence Comparison Table

	Jeil Medical Corporation Dual Top Anchor System Screws	Dentaurum Inc. Tomas PIN (Temporary Orthodontic Micro anchor system)	Bernhard Forster GmbH Ortho Easy PIN
Intended use	This device is intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only. For use in adults over the age of 12.	This device is intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only.	This device is intended to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended for single use only.
Indications for use	See intended use	See intended use	See intended use
Target population	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction
Anatomical sites			
Location of use (hospital, home, ambulance, etc)	Use only for professional dentists or orthodontics.	Use only for professional dentists or orthodontics.	Use only for professional dentists or orthodontics.
Energy used and/or delivered	NA	NA	NA
Human factors			

Design	diameter ranges from 1.4 - 2 mm, length ranges from 6 - 12 mm	diameter 1,2 mm, length ranges from 6 - 10 mm	diameter 1.7 mm, length ranges from 6 - 12 mm
Performance	self-trapping/self-drilling screw	self-drilling screw	self-trapping/self-drilling screw
Standards met	ISO 7405	ISO 7405	ISO 7405
Materials	titanium alloy ASTM F 136	TITAN grade 5 3.7165	titanium alloy ASTM F 136
Biocompatibility	Titanium alloy in medical grade according ASTM- F 136 is accepted for endosseous implant	Titanium alloy in medical grade according ASTM- F 136 is accepted for endosseous implant	Titanium alloy in medical grade according ASTM- F 136 is accepted for endosseous implant
Compatibility with the environment and other devices	Medical grade titanium alloy according to ASTM- F 136 is accepted for endosseous implants	Medical grade titanium alloy according to ASTM- F 136 is accepted for endosseous implants	Medical grade titanium alloy according to ASTM- F 136 is accepted for endosseous implants
Sterility	non-sterile	non-sterile	non-sterile
Electrical safety	NA	NA	NA
Mechanical safety	tensile strength of material according to ASTM F-136, Relevant diameter range 1.4 mm - 2 mm	tensile strength of material according to ASTM F-136	tensile strength of material according to ASTM F-136, diameter 1,7 mm, fracture-proof during implantation. See also material test reports comparing torque in different materials.
Chemical safety	NA	NA	NA
Thermal safety	NA	NA	NA
Radiation safety	NA	NA	NA



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

Forestadent Bernhard Forster GmbH
C/O Ms. Tanya O'Brien, RN/BSN/CPAN
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AJW Technology Consultants, Incorporated
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Apollo Beach, Florida 33572

JUN - 3 2011

Re: K110275
Trade/Device Name: Ortho Easy Pin
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: May 20, 2011
Received: May 23, 2011

Dear Ms. O'Brien:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110275

Device Name: Ortho Easy Pin

Indications For Use: The device is intended to provide a fix anchorage point for attachment of orthodontic appliance to facilitate the orthodontic movement of the teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The screws are intended to be single used only.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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