

K042965

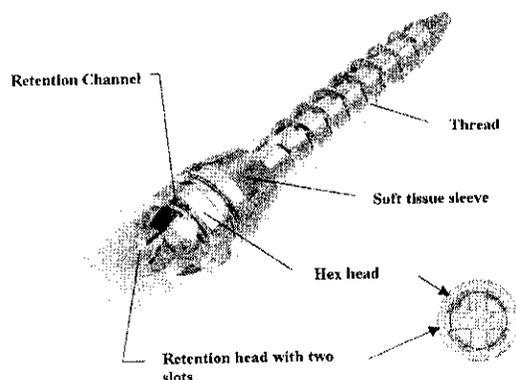
APR 15 2005

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Revised September 1, 2004
Contact: Dr. Thomas Lietz, R&D Director
510(k) Summary of Safety and Effectiveness

- (1) Identification of the Device:
Proprietary-Trade Name: tomas-pin (Temporary Orthodontic Micro Anchorage System)
Classification Name: Implant, Endosseous, Product Code DZE
Common/Usual Name: Bone Screw
- (2) Equivalent legally marketed devices: OsteoMed Orthodontic Screw System (K031936), Straumann Ortho Implant (K982509), Nobel Biocare Implant Orthodontic Anchor System (K000643), and the Jeil Medical Corporation Dual Top Anchor System Screws (K033767) ...
- (3) Indications for Use (intended use): Tomas-pins are temporary, enossal anchorage elements for the treatment of tooth abnormalities in orthodontics and pre-prosthetics.
- (4) Description of the Device: tomas-pin micro screws (orthodontic micro implant) are precisely manufactured, anchorage elements made of grade 5 titanium (3.7165), according to ASTM (American Society for Testing and Materials). They are inserted into the bone and serve as a temporary anchor for various orthodontic tooth movements. The tomas-pin is constructed as follows: The head of the screw features hex type slots. Rectangular wires are inserted to accommodate orthodontic elements, such as arches, elastic bands and brackets. Preferably, the wire should be fixed on the tomas-pin with light cured adhesive. The adhesive should completely/fully enclose the wire and retention head. The retention channel below the slots serves to securely anchor the adhesive to the tomas-pin. This also protects the soft tissue (cheek, lips, tongue) against irritation that could result from the screw head.

The thread of the tomas-pin is self-tapping but not self-drilling, which means that pre-drilling according to the length and diameter of the tomas-pin is necessary to accommodate the tomas-pin. The tomas-pin is inserted and screwed into the bone by either manual or mechanical method.

The shoulder connection between the thread and soft tissue sleeve serves as a stop to prevent the tomas-pin from sinking into the soft tissue. The soft tissue sleeve between the thread and retention head helps to prevent irritation between the gingiva and the tomas-pin, therefore, ensuring optimal hygiene.



Picture:

- Retention channel
- Thread
- Soft tissue sleeve
- Hex head
- Retention head with two slots

The tomas-pins are delivered in glass sterile ampoules. The package contains labels that can be inserted into the patient's file for future reference and tracking.

The tomas-pins are available in the following sizes:

Tomas-pin 08 (Order No. 302-008-00)
Length of screw body: 8mm
Diameter: 1.2mm

Tomas-pin 10 (Order No. 302-010-00)
Length of screw body: 10mm
Diameter: 1.2mm

Other product specifications can be found in the "Instructions for Use and Product Brochure".

(5) Indications for Use:

To provide a fixed anchorage point for attachments of orthodontic appliances.

(6) Potential Adverse Affects and Complications: (Common to all devices of this type)

- Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone, leading to nonunion.
- Migration, bending, fracture or loosening of the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Pain, discomfort or abnormal sensation, due to the presence of the device.
- Increased fibrous tissue response around the fracture site and/or the implant.
- Necrosis of bone.
- Inadequate healing.

Apart from these adverse affects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

(7) Safety and Effectiveness, comparisons to predicate devices:

Device Name	Nobel BioCare Implant Orthodontic Anchor System	OsteoMed Orthodontic Screw System	Jeil Medical Corp. Dual Top Anchor System Screws (various models)	Dentaurum, Inc. tomas-pin (Temporary Orthodontic Micro Anchorage System)
Device Classification Name	Implant, Endosseous, Product Code DZE	Implant, Endosseous, Product Code DZE	Implant, Endosseous, Product Code DZE	Implant, Endosseous, Product Code DZE
Applicant	Nobel BioCare	OsteoMed	Jeil Medical Corp.	Dentaurum, Inc.
510(K) Number	(K000643)	(K031936)	(K033767)	(this submission)
Material	Titanium	Titanium Alloy	Titanium Alloy (ASTM F 136-98)	Titanium Grade 5 (ASTM)
Intended Use	This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed.	This device is used as an anchorage for orthodontic treatment in the mouth.	This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed.	This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed.

	Screws are intended for single use only.		Screws are intended for single use only. For use in adults over the age of 12.	Screws are intended for single use only.
Single Use?	YES	YES	YES	YES
Supplied Sterile?	No comment	Non sterile, steam sterilize before use	Non sterile, steam sterilize before use	Sterile

- (8) Conclusion: In all reports, the tomas-pin (Temporary Orthodontic Micro Anchorage System) is the equivalent of currently marked devices. They are made of the same materials and have similar dimensions and characteristics. Potential adverse affects are identical to those of predicate devices. This device is manufactured from titanium, grade 5 (ASTM) that is used generally in this kind of bone screw. Similar devices made from titanium alloy (ASTM 136-98) to this device are manufactured and sold around the world. This device is substantially equivalent in design, material, intended use and function to the products on the table above. These devices are certified by the notified body for CE.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Dr. Thomas Lietz
R&D Director
Dentaurum, Incorporated
10 Pheasant Run
Newtown, Pennsylvania 18940

Re: K042965
Trade/Device Name: TOMAS Pin
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: April 6, 2005
Received: April 8, 2005

Dear Dr. Lietz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

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 K042965:

Device Name: TOMAS pin

Indications For Use: Temporary Orthodontic Micro Anchorage

Prescription Use
(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 IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Mulyan MSR

(For Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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