

NOV 18 1997

K973180

510 (k) SUMMARY

SUBMITTED BY:

**M. K. Patterson, Jr., PhD
Sr. Vice President
Regulatory Affairs
IMTEC Corporation
2401 North Commerce
Ardmore, Oklahoma 73401
(405) 223-4456**

**F.D.A. Registration Number: 1645158
Owner / Operator Number: 9003407**

Date Submitted: August 20, 1997

CLASSIFICATION/COMMON OR USUAL NAME/DEVICE NAME:

**Classification Name: Smooth or threaded metallic bone fixation fastener
(ref: 21 CFR 888.3040); Product Code: DZL
Common/Usual Name: Bone Tack, Bone Screw or Bone Fixation Device.
Proprietary Name: IMTEC Bone Tac**

PREDICATE DEVICE:

**Interpore International, IMZ Bone Tack System, K952167
Interpore International, IMZ Membrane Tack System, K960945**

DEVICE DESCRIPTION:

The IMTEC Bone Tac is fabricated of titanium alloy and has a thin low profile head and a barb at the tip for stabilization. It is designed to stabilize guided tissue membranes during the healing process by providing an attachment mechanism to the adjacent bone at the surgical site. The device will be marketed non-sterile.

INDICATIONS FOR USE:

The IMTEC Bone Tac System is designed to stabilize a Barrier Membrane onto a region of cortical plate. This may be used in craniofacial, maxillofacial or mandibular bone. Considerations such as quality of bone, bone type, functional loads exerted, general patient health and others should be carefully evaluated prior to use.

PRINCIPLES OF OPERATION:

- 1. An aseptic technique is required for predictable success.**
- 2. The tacs and instrumentation are provided NON-STERILE and must be appropriately sterilized prior to use.**
- 3. Remove the cap from the seating instrument. Firmly press the seating instrument onto the head of the desired length tac in the tac holder. This will purchase the tac to be carried to the placement site. Seat the tac through the barrier material only with the tip of the seating instrument perpendicular to the bone surface or the tac may be damaged. Placement should be accomplished with a single firm tap on the base of the seating instrument with the mallet. To disengage the tac, roll the seating instrument to one side. If the tac is not completely seated after the first mallet strike, place the protective cap on the seating instrument and complete the process by tapping on the seating instrument with the cap positioned against the tac head. The seating instrument may be damaged if it is repeatedly struck with the tac in the "held" position.**
- 4. Repeat this process until the barrier is firmly anchored. Always store the seating instrument with the cap in place. Otherwise, it may become distorted and not able to purchase the tac head.**
- 5. A pilot drill hole may be required in areas of dense cortical bone. The twist drill required for this process is delicate and must be used with a cautious and light pressures to prevent fracture. A pilot hole should be placed through laminar bone when it is being used as the barrier.**
- 6. Suture the soft tissue in the usual manner when the surgical procedure is complete. Every effort should be made to assure primary closure of all areas.**
- 7. Radiographs should be taken to document the number and position of the tacs. This information should also be noted in the patient's record.**
- 8. In instances where tac removal is required, after normal surgical exposure the tacs may be dislodged by using a surgical scalpel, periosteal elevator or other similar thin flat instrument. The tacs should be removed, inventoried and discarded. REUSE IS NOT RECOMMENDED. The surgical site is now resutured.**

CONTRAINDICATIONS:

General patient evaluation is critical prior to any surgical procedure. Contraindications include, but are not limited to, vascular impairment, systemic or local infection, diabetes, radiation, steroid, or anticoagulant therapy, clotting disorders or other systemic or metabolic limitations which would compromise healing.

COMPLICATIONS:

Complications include those associated with any osseous surgical procedure and an esthetic usage. Type and severity of complications may indicate tac removal at the discretion of the clinician.

MATERIALS OF CONSTRUCTION:

Bone Tac	Titanium 6Al-4V ELI
Bone Tac Instrument	
Handle	303 Stainless Steel
Tip and Cap	Titanium 6Al-4V
Autoclavable Tac Holder	
Stainless Steel w/Titanium Inserts	303 Stainless Steel/Titanium 6Al-4V
Cover	Polycarbonate (Autoclavable)
Bone Tac Mallet	
Handle and Head	Stainless Steel

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The design, material, configuration, method of sterilization and other technological characteristics of IMTEC Bone Tac are similar to the currently marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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M.K. Patterson, Jr., Ph.D.
Sr. Vice President Regulatory Affairs
Imtec Corporation
2401 North Commerce
Ardmore, Oklahoma 73401

Re: K973180
Trade Name: Imtec Bone Tac
Regulatory Class: II
Product Code: DZL
Dated: August 20, 1997
Received: August 25, 1997

Dear Dr. Patterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

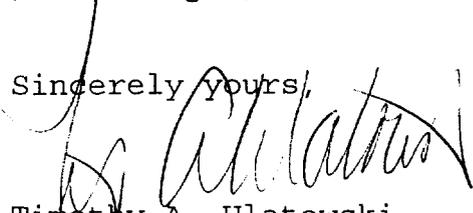
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: IMTEC BONE TAC SYSTEM

Indications For Use:

The IMTEC Bone Tac System is designed to stabilize a Barrier Membrane onto a region of cortical plate. This may be used in craniofacial, maxillofacial or mandibular bone. Considerations such as quality of bone, bone type, functional loads exerted, general patient health and others should be carefully evaluated prior to use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number 1K973780

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____