NOV 19 1997

K973248

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: September 1, 1997

CLASSIFICATION/COMMON OR USUAL NAME/ DEVICE NAME:

Classification Name: Non-powered, portable suction apparatus.
Common/ Usual Name: Suction Powered Oral Cavity Evacuator.
Proprietary Name: IMTEC Bone Collector System.

PREDICATE DEVICE:

ODONTIT, The ODONTIT Autogeneous Bone Collection Device, K971036.

DEVICE DESCRIPTION:

The IMTEC Bone Collector System is designed to facilitate the collection of autogeneous bone for use in augmentation procedures. Adapted from an oral suction device it contains a filter cartridge which traps bone particles resulting from drilling into bone. The filter can be removed and the bone particles asceptically collected. The filters are available either sterile/single use or autoclavable. The autoclavable filter cartridge is not recommended for reuse in bone collection augmentation procedures.

INDICATIONS FOR USE:

The IMTEC Bone Collector System is designed to facilitate the collection of autogenous bone particles for use in augmentation procedures. This is accomplished by introducing into the surgical suction line a housing and filter apparatus. Autogenous bone particles which would otherwise be loss into the suction system are trapped in this filter. This material may be easily retrieved for usage.

PRINCIPLES OF OPERATION:

The IMTEC Bone Collection utilizes an oral suction device to asceptically trap particulate autogenous bone, which can be used as unadulterated bone filling material or as a mixture with other natural or synthetic filling materials.

CONTRAINDICATIONS:

Contraindications customary to the use of bone grafting materials should be observed. These include but are not limited to, current local infection, vascular impairment at the surgical site, uncontrolled diabetes, chronic high dose steroid therapy, clotting disorders, current anticoagulant therapy, metabolic bone disease, and other metabolic or systemic disorders which affect bone or wound healing.

COMPLICATIONS:

Possible complications with any oral reconstructive surgery include infection, closure perforation, abscess formation, bone loss, pain, soft tissue irregularities, and additional complications associated with anesthesia and dental surgery. There should be few specific complications resulting from the use of autogeneous bone.

MATERIALS OF CONSTRUCTION:

Bone Collector Housing	**Aluminum 6061**
Filter Cartridge, Sterile	
Screen	**150 micron Polyester**
Support material	**ABS Lustran 248-2002**
Filter Cartridge, Autoclavable	
Screen	**150 micron Polyster**
Support material	**Polypropylene**
O-Rings	**Nitrile, Hydrogenated**

WARNING:

Surgical techniques required for bone augmentation procedures are highly specialized and complex. Specialized training is strongly recommended. Practitioners should attend courses of study to prepare them in established techniques. Improper technique can cause graft failure or loss of bone.

PRECAUTIONS:

Aseptic Technique required. Establish the location of all anatomical features to be avoided prior to initiating any dental surgical procedure.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed dentist or physician, and use by any other person is prohibited.

For technical assistance, and more information or to order please call our toll free number: (800) 879-9799 or (405) 223-4456. The address is as follows:

IMTEC Corporation
2401 North Commerce
Ardmore, Oklahoma 73401

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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
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2401 North Commerce
P.O. Box 1562
Ardmore, Oklahoma 73401

Re: K973248
Trade Name: Imtec Bone Collector System
Regulatory Class: I
Product Code: EZH
Dated: August 29, 1997
Received: August 29, 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): K973248

Device Name: IMTEC BONE COLLECTOR SYSTEM

Indications For Use:

The IMTEC Bone Collector System is designed to facilitate the collection of autogenous bone particles for use in augmentation procedures. This is accomplished by introducing into the surgical suction line a housing and filter apparatus. Autogenous bone particles which would otherwise be loss into the suction system are trapped in this filter. This material may be easily retrieved for usage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Gerald Shupp
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973248

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)