

K972351

PREMARKET NOTIFICATION [510(k)] SUMMARY

Safe Medical Devices Act Summary of Safety and Effectiveness

Submitter: Sendax MDIC Management, Inc.

NOV 24 1997

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Contact Person: Dr. Victor I. Sandax

Date of Summary Preparation: May 31, 1997

Classification Name & Number: Endosseous Dental Implant 76DZE

Common/Usual Name: Dental Anchor Post/Endodontic Splint-Stabilizer/  
Mini Transitional Implant

Name of Device: Mini Dental Implant, cp titanium or titanium alloy

Proprietary (Trade) Name: Sendax MDI™

Legally Marketed Device Claimed As Substantially Equivalent:  
Dentatus MTI™ Anchor Post/Modular Transitional Implant

Description of Device: Self-tapping titanium threaded screw, 1.8mm in  
width by 14,17,19,&22mm lengths

Intended Use of Device: To provide immediate transitional splinting stab-  
ility or ongoing fixation of new/existing crown,  
bridge & denture installations in partial or  
fully edentulous settings

Technological Characteristics: Comparable biocompatible titanium mater-  
ials, manufacture, sterilization methods, and  
intended applications

Clinical performance data: Based on a twenty-year prospective clinical  
study commencing in 1976 by Sendax & associates,  
demonstrating consistent quality as well as  
quantity of survival, confirming safety and  
efficacy of the Sendax insertion/reconstructive  
protocol

Decision Tree: Based on the 510K substantial equivalence decision-making  
process from ODE Guidance Memo No. 86-3

End of Summary



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Victor I. Sendax, DDS  
President & CEO  
Sendax MDIC Managemner, Incorporated  
30 Central Park South, Suite 4B  
New York, New York 10019

NOV 24 1997

Re: K972351  
Trade Name: Sendax MDI (Mini Dental Implant)  
Regulatory Class: III  
Product Code: DZE  
Dated: October 3, 1997  
Received: October 6, 1997

Dear Dr. Sendax:

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.

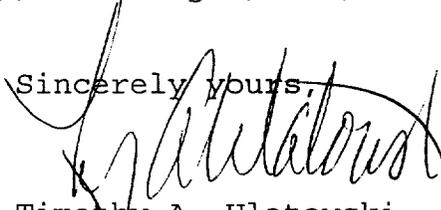
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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: 972351

Device Name: SENDAX MINI DENTAL IMPLANT (MDI)

Indications For Use: This device is a self-tapping titanium threaded screw indicated for intra-bony and inter-radicular transitional applications, to permit immediate splinting stability and ongoing fixation of new or existing crown & bridge installations, for full or partial edentulism, and employing minimally invasive surgical intervention.

Representative applications include the following:

- \* Temporary (transitional) supports for fixed or removable implant-supported prostheses while conventional implants are integrating.
- \* Stabilizing interim prostheses in graft sites and guided tissue regeneration applications to avoid iatrogenic damage to healing grafts, membranes or integrating implants.
- \* Introductory system for nervous or apprehensive potential implant patients, offering a simple methodology for testing out the actual "feel" of bone-anchored implants, without the major commitment to final restorations; or as an interim system for medically compromised, handicapped or terminally ill patients to enhance their comfort by maintaining a reasonable level of speech, mastication & general well-being, at modest cost levels.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number 972351

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)