

XIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA. (Separate Pages)

A. Submitter: Stephen B. Rubinsky, Dentatus USA, Ltd. 192 Lexington Ave., New York, N.Y., 10016. Registration No. 2435118.

I. Classification Name and Number: Endosseous Implant (76DZE),

II. Common/Usual Name: Dental Implant, Endosseous, Post (or screw)-type, titanium or titanium alloy.

III. Proprietary Name: Dentatus Transitional Implants, MTI-MP™.

IV. Classification: These devices were classified by the Dental Devices Panel (Title 21 CFR 872.3640.

V. Performance Standards: None applicable. All metals meet ASTM specifications including ASTM F-136 for the titanium (ELI) alloy and ASTM F 67-95 for pure titanium.

VI. Description: The Dentatus Mini Transitional Implants (MTI™) are titanium or titanium-alloy threaded posts, 1.8 mm to 2.5 mm in diameter and from 14 to 22 mm. in length. There are variations; they are threaded at the bottom-self-tapping, and the "head" is of slightly varying shapes.

VII. Labels and Instructions for use are provided as are labels for competitive products.

VIII. Intended use: These devices are intended to be placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices and to restore the patient's chewing function.

IX. Substantial Equivalence: This device is equivalent to devices manufactured and sold before 1976, having a U. S. classification number of 76 DZE and described under CFR 872.3640. It is also equivalent to several devices currently on the market that have been determined by the FDA to be substantially equivalent to the above preamendment devices. This device is equivalent (and nearly identical) to the Sendax MDI implant cleared by K-972351. Its shape, form, composition, and usage are nearly identical to those cleared in K-972351. These devices are manufactured of high-purity (99+ %) titanium, or titanium alloy (ASTM F 136-84 titanium - 6 aluminum - 4 vanadium). The excellent biocompatibility and wear characteristics of titanium and this alloy have been demonstrated by the long history of their use in surgical and dental prothesis. In its transitional mode, this device is substantially equivalent (nearly identical) to the device of Sendax MDIC Management, New York, N.Y., "Sendax MDI, K-972351. In its extended use this device is substantially equivalent to the many endosseous implant devices of the screw or cylinder type that have been cleared under a variety of 510(k)s. Several of these are listed below.

1. Bofors Nobelpharma, Goteborg, Sweden: Titanium Implant Device, K-820013.
2. Sherwood, St. Louis, Mo: Monoject Endosseous Dental Implant, K-781060A.
3. Core-Vent Corp., Encino, CA: Screw-Vent Endosseous Implants, K-861426, A, B.
4. Impla-med, Inc., Sunrise, FL: P.M.T. Surgical Implant Components, K892124A, (Titanium Grade 3, ASTM F67-83); K-921854 and others.
5. Steri-Oss (Subs. Denar, Anaheim, CA.), Denar Dental Implant, K-852802; Steri-Oss Implant, K-884845.
6. Artech, Inc., Chantilly, VA: Artech Submerged Screw Implant, K-891346, K-895267.
8. Odontit, SA, Buenos Aires, Argentina: Osseointegrated Implants System, K-915375.

X. Brief Literature Review: Detailed literature surveys were made of the typical endosseous implant in its many forms and of the transitional use of endosseous implants.

The possible adverse effects summarized in this 510(k) cover those listed by the United States classification panel [Federal Register, vol. 45, No. 251, pp 86025-6, Dec. 30, 1980], as well as to those revealed in a recent literature search. Matukas, "Medical Risks Associated with Dental Implants," states, "Little or no hard data could be found on the medical risks associated with [dental] implants." Because of the wide-spread usage of dental implants, Smith and Zarb made a careful review of the literature and proposed criteria for implant success.

The Journal of Dental Education published a special issue "Proceedings of the Consensus Development Conference on Dental Implants [National Institutes of Health, Bethesda, MD, June 13-15, 1988], Vol. 52, No. 12, pp. 677-831, Dec. 1988. This added to the literature search above, with some especially pertinent reprints from the scientific literature, provide a comprehensive summary of available scientific data.

Zarb completed his report of the detailed Toronto 10-year study by concluding that "the tried and tested Branemark implant technique has revolutionized the treatment options open to the prosthodontist. For the edentulous patient...the prospect for a lifetime of restored oral comfort, function, and appearance have now become predictable and reliable." These results are ample evidence of the safety and effectiveness of these endosseous implants.

A literature search of the "transitional" use of endosseous implants shows the rapidly developing interest of implantologists in making the application of endosseous implants less traumatic. Gottherer and Singer report on effective means for preliminary stabilization of full denture patients.

These devices are manufactured from the titanium materials proved effective by the above summarized years of clinical usage, are sterilized by the standard methods, and are meant for use according to methods in the cited substantially equivalent products. Thus, they involve no new types of technology and no new technological questions.

END OF SUMMARY



MAY 15 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Stephen B. Rubinsky
President
Dentatus USA, Ltd.
192 Lexington Avenue
New York, New York 10016

Re: K980620
Trade Name: Dentatus MTI Modular Transitional Implants
and Prosthetic
Regulatory Class: III
Product Code: DZE
Dated: February 14, 1998
Received: February 18, 1998

Dear Mr. Rubinsky:

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 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). 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 requirements, 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

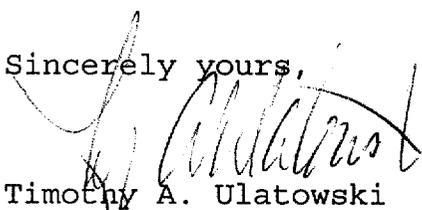
Page 2 - Mr. Rubinsky

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) 594-4692. 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" (21CFR 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/dsma/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

VII.2 Indications for Use: [Separate Page]

510(k) Number: K980620

Device Name: ~~DENTATUS MTL MODULAR TRANSITIONAL IMPLANTS~~

Intended to be placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

Examples:

Support anchors for temporary restorations during the healing and osseointegration process of permanent implants.

Immediate loading temporary abutments for repairing failing tooth and implant supported restorations.

Transitional supports for immediate replacement of missing teeth.

Provide assistance in case planning, implant position alignments, and interim anchor foundations.

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

[Signature]
Concurrence of ~~ODE~~ Office of Device Evaluation (ODE)

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

510(k) Number K980620

Prescription Use
(Per 21 CFR 801.109)

or

Over-The-Counter Use

(Optional Format 1-2-96)

(repl. p. 5)