DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1999

Ms. Marci Bloom
President
The Dental Medical Device Company, L.L.C.
39 Aynsley Court
Montville, New Jersey 07045

Re: K981997
Trade Name: Posi-Stop/Posi-Trac System
Regulatory Class: III
Product Code: DZE
Dated: October 8, 1998
Received: October 14, 1998

Dear Ms. Bloom:

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 (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 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

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

Device Name: Posi-Stop/Posi-Trac System

Indications For Use:

The Posi-Stop/Posi-Trac System consists of 12 drills plus a starter drill utilized in osteotomy procedures before implant insertion.
The Posi-Stop/Posi-Trac System is designed for use with or without a surgical guide. The system allows the dental practitioner to increase size gradations in 0.5mm steps for final sizing for implant type customization.

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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

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

(Optional Format 1-2-96)

Susan Runyon

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981997

K981997

510K Number: K981997
Device Name: Posi-Stop/Posi-Trac System
Indications for Use con't. p. 2

The Posi-Stop/Posi-Trac System is designed for use with or without a surgical guide. The system is truly generic in that its 0.5mm size gradations allows the doctor to switch to a final sizing drill for implant type customization.

*Osteotomy preparation is begun with a 1.6mm starter drill. The depth of the preparation should pierce the outer cortical bone and be about 5mm in depth. If a surgical drill guide is used, the guide tube should have an inside diameter of 1.6mm and the starter drill should be tested in the guide tube to be certain that binding does not occur.

*The length adjusted 1.6mm drill is placed into the osteotomy preparation and to the correct depth. It must be remembered the 1.6mm drill is the only depth cutting instrument; the remaining drills cut only on the outer 0.5mm to prevent excessive depth penetration. It is recommended that the osteotomy be prepared 1-2mm deeper than the length of the implant to allow for the exact placement of the coronal aspect of the implant in relation to the crestal bone.

*After the 1.6mm osteotomy is prepared, a 2mm Posi-Trac drill is utilized. The pilot end of this instrument is 1-6mm (the diameter of the previous drill) and will fit easily into the osteotomy. The Posi-Trac drill is 8mm in length and should be used only to widen the osteotomy to the next drill size. It should not be taken to length. After use of the Posi-Trac, the next length adjusted Posi-Stop instrument will be utilized until the correct width is achieved.

*Should during the course of preparation, the Posi-Stop (PSD 2) not fit interdentally, it may be removed by moving the Posi-Stop (PSD 2) to the colored size indicator ring (PSD 10) along the track guide (PSD 5). The stop is rotated away from the operator until the locking screw assembly (PSD 2b) is on the drill flute, then removed by pulling it along the drill flute and over the cutting end. The Posi-Stop is simply replaced by reversing the procedure. The osteotomy can still be prepared safely since the 2.0 - 4.5mm sizes are safety ended.