



JUN 25 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. William Simmons  
Vice President Technical Support  
Healthline Implants, Incorporated  
832 Marseilles-Galion Road West  
Marion, Ohio 43302

Re: K981954  
Trade/Device Name: Various Dental Implants with Various Abutments  
Regulation Number: 872.3640  
Regulation Name: Blade-form endosseous dental implants  
Regulatory Class: III  
Product Code: NRQ  
Dated: December 2, 1998  
Received: December 3, 1998

Dear Mr. Simmons:

This letter corrects our substantially equivalent letter of January 25, 1999 regarding the product code. Blade implants have been moved to a separate product code from root-form implants due to the reclassification of root form implants..

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In

Mr. Simmons

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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 Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K981954  
Device Name: Various Dental Implants with various abutments

Indications For Use:

The implant(s) is designed for use in the edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed or partial dentures, or a single tooth replacement.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

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

(Optional Format 1-2-96)

Michael Shapiro  
(Division Sign-Off) for MSR  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K981954

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