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510(k) SUMMARY

K073073

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT: Helen Lewis

DATE PREPARED: October 29, 2007

TRADE OR PROPRIETARY NAME: ANKYLOS® Temporary Abutment Balance

CLASSIFICATION NAME: Endosseous dental implant abutment (872.3630)

PREDICATE DEVICES: FRIADENT® EsthetiCap Abutment, K050208
ANKYLOS® Balance Abutment, K041509

DEVICE DESCRIPTION: The ANKYLOS® Temporary Abutment Balance is part of the ANKYLOS® Dental Implant System. The temporary abutment is available in the sizes "small" (D5.5) and "large" (D7) and with the gingival margins of 1.5 and 3. The ANKYLOS® Temporary Abutment Balance can be used in straight and angled implant positions.

INTENDED USE:
The ANKYLOS® Temporary Abutment Balance is an anatomical abutment indicated for the fabrication of provisional crowns or bridges over max. 2 bridge pontics. The ANKYLOS® Temporary Abutment Balance is a short-term provisional for esthetic soft-tissue contouring.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in the ANKYLOS® Temporary Abutment Balance have been used in legally marketed devices and/or were found safe for dental use. The ANKYLOS® Temporary Abutment Balance is made of plastic material, which has been evaluated and passed biocompatibility testing for cytotoxicity. The materials used for the ANKYLOS® Temporary Abutment Balance as well as the manufacturing methods are identical to legally marketed devices. Therefore it was determined that no additional biocompatibility testing for the final product was necessary.

We believe that the prior use of the components of the ANKYLOS® Temporary Abutment Balance in legally marketed devices, the performance data provided, and the previous biocompatibility tests support the safety and effectiveness of the ANKYLOS® Temporary Abutment Balance for the indicated uses.

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TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87(k))

I certify that, in my capacity as Director of Corporate Compliance and Regulatory Affairs of DENTSPLY International, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Helen Lewis
Director of Corporate Compliance and Regulatory Affairs

October 29, 2007

K_____ ANKYLOS® Temporary Abutment Balance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2008

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International, Incorporated
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K073073
Trade/Device Name: ANKYLOS® Temporary Abutment Balance
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 5, 2008
Received: February 7, 2008

Dear Ms. Lewis:

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 application (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.

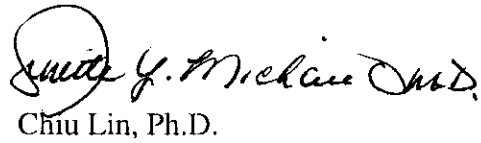
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 begin 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

1081

INDICATIONS FOR USE

K073073

510(k) Number (if known): K073073

Device Name: ANKYLOS® Temporary Abutment Balance

Indications for Use:

The ANKYLOS® Temporary Abutment Balance is an anatomical abutment which is indicated for the fabrication of provisional crowns or bridges over max. 2 bridge pontics. The ANKYLOS® Temporary Abutment Balance is a short-term provisional for esthetic soft-tissue contouring.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K073073