K083805

1 of 2

DENTSPLY

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
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MAY 22 2009

510(k) SUMMARY
for
Title of Submission

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: December 19, 2008

2. Device Name:

- Proprietary Name: ANKYLOS® C/X Dental Implant System
- Classification Name: Endosseous dental implant
- CFR Number: 872.3640
- Device Class: II
- Product Code: DZE

3. Predicate Device:

Company	Device	510(k) Number	Date Cleared
DENTSPLY International Inc.	ANKYLOS® plus Dental Implant System	K041509	08/26/2004
DENTSPLY International	Friadent Implant Systems	K073075	03/31/2008

4. Description of Device:

The new ANKYLOS® C/X Dental Implant System introduces a new configuration of the current ANKYLOS® plus dental implant line. The new line extension includes the: ANKYLOS® C/X Implant, ANKYLOS C/ Regular Abutments, ANKYLOS /X Regular Abutments, ANKYLOS® Regular C/X Gingiva Former, and the ANKYLOS® Titanium Alloy Screws (Membrane Screw and Fixation Screw).

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The ANKYLOS® C/X Dental Implant was modified to integrate an indexation into the taper connection to provide a precise position of the abutment. With the new index, the relocation of the abutment is possible without using a transfer-key for the impressions taking.

5. Indications for Use:

The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.

6. Description of Safety and Substantial Equivalence

Technological Characteristics

All of the components found in ANKYLOS® C/X Implant System have been used in legally marketed devices and were found safe for dental use. The ANKYLOS® C/X Dental Implant System consists of root-formed threaded screws made from commercially pure titanium. The material used for the ANKYLOS® C/X Implant System, as well as the manufacturing methods, are identical to legally marketed devices.

Non-Clinical Performance Data

The results regarding the fatigue tests of the ANKYLOS® C/X Implant and the predicate devices were comparable. Therefore, it concluded that the ANKYLOS® C/X Implant performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Helen Lewis
Dentsply International, Incorporated
Dentsply Tulsa Dental
Susquehanna Commerce Center
221 West Philadelphia Street
York, Pennsylvania 17404

MAY 22 2009

Re: K083805
Trade/Device Name: ANKYLOS® C/X Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 19, 2009
Received: May 20, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K083805

Device Name: ANKYLOS® C/X Dental Implant System

Indications for Use:

The ANKYLOS® C/X Dental Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Dental Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.

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)

Kim Mealey for NSR

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

510(k) Number: K083805