DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2014

Dentsply International, Inc.
Ms. Helen Lewis
Director Corporate Regulatory Affairs
221 West Philadelphia Street
Suite 60
York, PA 17404

Re: K140347
Trade/Device Name: ANKYLOS® C/X Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE
Dated: July 21, 2014
Received: July 23, 2014

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): __K140347_____

Device Name: ANKYLOS® C/X Implant System

Indications for Use:

ANKYLOS® C/X lmplants of **8 mm in length or longer** are for single-stage or two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X lmplants may be used for immediate placement and function on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted.

ANKYLOS® C/X lmplants of **6.6 mm in length** are for two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X lmplants may be used for immediate placement on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted.

| | | |
|---|---|---|
| Prescription Use ___X___<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(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)

## SECTION 5. 510(k) SUMMARY

**for**
**ANKYLOS® C/X Implant System**

1. Submitter Information**:**

DENTSPLY International, Inc.
221 West Philadelphia Street, Suite 60
York, PA 17404

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: February

2. Device Name:

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

3. Predicate Device:

- ANKYLOS® C/X Dental Implant System cleared in K083805
- Bicon Implant 4.0 x 5.0 mm cleared in K092035 (Bicon Implants with a 2.5 mm Internal Connection)

4. Description of Device:

The ANKYLOS® C/X Implant 6.6 mm represents a line extension of the currently marketed ANKYLOS® C/X Dental Implant System. It is an endosseous dental implant with a length of 6.6 mm and an internal tapered implant-abutment connection. The ANKYLOS® C/X Implant 6.6 mm is machined from Commercially Pure (CP) Grade 2 Titanium (conforming to ASTM F67 -Standard Specification for Unalloyed Titanium, for Surgical Implant Applications). The ANKYLOS C/X 6.6 mm implants are provided in the diameters 3.5 mm, 4.5 mm, and 5.5 mm.

5. Indications for Use:

ANKYLOS® C/X lmplants of **8 mm in length or longer** are for single-stage or two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X lmplants may be used for immediate placement and function on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted.

ANKYLOS® C/X lmplants of **6.6 mm in length** are for two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X

lmplants may be used for immediate placement on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.

The material used for the ANKYLOS® C/X Implant 6.6 mm is the same CP Grade 2 titanium material as is used in the legally marketed predicate device, ANKYLOS C/X Dental Implant System (K083805). The proposed devices are similar in terms of design, sizes, indications for use and incorporate the same technological characteristics as the predicate devices (see Table 1).

In order to assure safety of the ANKYLOS® C/X Implant 6.6 mm, a Failure Mode, Effects Analysis has been performed. There were no unacceptable risks regarding the function of the ANKYLOS® C/X Implant 6.6mm.

Non-Clinical Performance Data.

Fatigue testing was conducted on the subject ANKYLOS® C/X Implant 6.6 mm in comparison to the predicate device according to ISO 14801 (*Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*). Further, surface area and bone to implant contact have been calculated by CAD data for the ANKYLOS® C/X Implant 6.6 mm and the predicate device, respectively. The results support substantial equivalence.

Conclusion as to Substantial Equivalence

Based on the comparison of the indications for use, the technological characteristics and the nonclinical testing it can be concluded that the ANKYLOS® C/X Implant 6.6 mm is substantially equivalent to the predicate devices.

Table 1: Similarities and Differences between the proposed and the predicate devices

| | Proposed Device<br>DENTSPLY ANKYLOS® C/X Implant System | Predicate Device<br>DENTSPLY ANKYLOS® C/X Implant System<br>(K083805) | Predicate Device<br>Bicon Implant 4.0 x 5.0mm<br>(K092035) |
|---|---|---|---|
| Indications for use | ANKYLOS® C/X lmplants of **8mm in length or longer** are for single-stage or two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X lmplants may be used for immediate placement and function on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted.<br><br>ANKYLOS® C/X lmplants of **6.6mm in length** are for two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X lmplants may be used for immediate placement on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted. | 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. | The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement. |
| Material Composition | Commercially Pure Titanium | Commercially Pure Titanium | Titanium Alloy |
| Implant-Abutment Connection | tapered | tapered | tapered |
| Implant Design / | Thread | Thread | Plateau Design |
| Diameter (mm) | 3.5/ 4.5/ 5.5 /6.5 | 3.5/ 4.5/ 5.5/ 6.5 | 4 mm |
| Length (mm) | 6.6/ 8/ 9.5/ 11/ 14/ 17 | 8/ 9.5/ 11/ 14/ 17 | 5.0 |
| Delivery | sterile | sterile | sterile |