K136644

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DENTSPLY

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SECTION 5.

510(k) SUMMARY
for
ANKYLOS® SynCone® Abutment 5°

1. Submitter Information:

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

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

Date Prepared: December 20, 2013

2. Device Name:

- Proprietary Name: ANKYLOS® SynCone® Abutment 5°
- Classification Name: Endosseous dental implant abutment
- CFR Number: 872.3630
- Device Class: II
- Product Code: NHA

3. Predicate Device:

- ANKYLOS® SynCone® Abutments 4° and 6°, cleared as part of the ANKYLOS® Dental Implant System (K041509)
- Angled ANKYLOS® Balance Base Abutments (K122268)

4. Description of Device:

The ANKYLOS® SynCone® Abutment 5° is an endosseous dental implant abutment which provides a platform for prosthetic restoration in conjunction with ANKYLOS® implants. The subject device incorporates an abutment head with a 5° conical taper and is provided in angulations of 0°, 7.5°, 15°, 22.5° and 30° and with gingival heights ranging from 1.5mm - 4.5mm. The abutment is connected to the corresponding implant by a central screw which mates with the internal thread of the implant. The abutment and the abutment screw are machined from Titanium Alloy (Ti6AL4V ELI) conforming to ASTM F136 (*Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial Alloy for Surgical Implant Applications*). The tapered SynCone® 5° caps which anchor the SynCone® abutment on the fixed denture are made of Gold Alloy or of Titanium conforming to ASTM F67 *(Standard Specification for Unalloyed Titanium, for Surgical Implant Applications)*. The SynCone® abutments feature a

reatining screw design which allows for the rotation of the abutment head after attachment to the implant in order to achieve rotational alignment for all of the abutments used in the prosthetic restoration.

The DENTSPLY SynCone® Abutments are intended for use with the implants of the DENTSPLY ANKYLOS® Dental Implant System (ANKYLOS® plus, ANKYLOS® C/X implants).

In addition to the introduction of the ANKYLOS® SynCone® Abutment 5°, a modification to the indications for use statements of the currently marketed ANKYLOS® SynCone® Abutments 4° and 6° (originally cleared in premarket notification K041509, ANKYLOS Dental Implant System) is implemented as part of this premarket notification.

5. Indications for Use:

Anchorage of dentures retained by taper friction and supported by ANKYLOS® implants.

Immediate loading of an implant supported prosthesis in an edentulous mandible supported by 4 ANKYLOS® implants of at least 11mm in length and placed interforaminally.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.

The material used for the ANKYLOS® SynCone® Abutments 5°, Ti6Al4V, is the same Titanium Alloy material as is used in the legally marketed predicate device. The proposed devices are similar in terms of design, angulations, sizes, indications for use and incorporate the same technological characteristics as the predicate devices. The design of the caps and the abutment cover screw corresponds to the abutments. The materials of composition for these accessory components are equivalent to existing, legally marketed accessory components and and the biocompatibility has been evidenced.

In order to assure safety of the ANKYLOS® SynCone® Abutments 5°, a failure mode, effect and criticality analysis has been performed. There were no unacceptable risks regarding the function of the ANKYLOS® SynCone® Abutments 5°.

Non-Clinical Performance Data.

Representative fatigue testing was conducted on the subject ANKYLOS® SynCone® Abutments 5° in comparison to the predicate device. The testing was conducted according to ISO 14801 (*Dentistry – Implants – Dynamic fatigue test for endosseous detnal implants*) and the results support substantial equivalence.

Pull force testing was conducted to verify the equivalence of the taper friction retention properties of the SynCone® Abutment 5° in comparison with those of the predicate

abutments. The results confirmed the equivalence of the performance of the new 5° abutment with that of the predicate devices.

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® SynCone® Abutments 5° are substantially equivalent to the predicate devices.

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

January 22, 2014

Dentsply International, Incorporated
Ms. Helen Lewis
Director Regulatory Affairs
221 West Philadelphia St.
Suite 60
York, PA 17404 US

Re: K131644
Trade/Device Name: Ankylos syncone abutment 5(degree)
Regulation Number: 21 CFR 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 23, 2013
Received: June 5, 2013

Dear Helen 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" (21 CFR 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,

Kwame O. Ulmer-S for

Erin I. Keith, M.S.
Acting 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): K131644

Device Name: ANKYLOS® SynCone® Abutment 5°

Indications for Use:

SynCone® Abutments on osseointegrated Implants
Anchorage of dentures retained by taper friction and supported by ANKYLOS® implants

SynCone® Abutments for immediate loading
Immediate loading of an implant supported prosthesis in an edentulous mandible supported by 4 ANKYLOS® implants of at least 11 mm in length and placed interforaminally.

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

Susan Runner DDS MA
Mary S. Runner -S
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