K101913

MAR 1 1 2011

510(k) SUMMARY

As required by section 807.92(c)

Submitter	**ANTHOGYR SAS** 2237, avenue Andre Lasquin SALLANCHES, FRANCE 74700 Registration Number:8020776
Contacts	Eric GENEVE e.geneve@anthogyr.com Phone (33) (0)4 50 58 02 37 Fax (33) (0)4 50 93 78 60 Regulatory: Dr Isabelle DRUBAIX (PhD) IDEE CONSULTING idrubaix@nordnet.fr
Preparation date	June 16, 2010
Trade Name	ANTHOGYR DENTAL IMPLANT SYSTEMS : AXIOM
Classification Name	ENDOSSEOUS DENTAL IMPLANT
Class	II
Product Code	DZE
CFR section	21CFR 872.3640
Device panel	DENTAL
Legally marketed predicate devices	PRIMACONNEX INTERNAL CONNECTION IMPLANT SYSTEM (KO51614)

Description

AXIOM dental implant system is designed to enhance the functional and aesthetic integration of implant supported restorations. AXIOM implants are made of grade V titanium and present a single connection (2.7 mm) common to all implant forms in the range. AXIOM implants are available in 4 diameters (3.4, 4.0, 4.6 and 5.2 mm) and various heights from 8 to 14 mm.

AXIOM dental implant system includes all required prosthetic components and surgical instrumentation.

Intended Use

ANTHOGYR Dental Implant System implant AXIOM is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

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Performance data

ANTHOGYR Endosseous dental implant system AXIOM conforms to Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments issued on May 12, 2004. Non clinical performance data presented within the submission included: Fatigue testing, Implant to abutment compatibility, corrosion testing and modified surfaces information.

Clinical data

None included

Substantial equivalence

ANTHOGYR Endosseous dental implant system AXIOM is substantially equivalent to its predicate device in terms of intended use, material, design, mechanical properties and function.

<table>
<tr><th></th><th>AXIOM</th><th>PRIMACONNEX (K051614)</th></tr>
<tr><td>21CFR / Product's code / Panel</td><td colspan="2">21CFR 872.3640 / DZE / DENTAL PANEL</td></tr>
<tr><td>Indications for use statement</td><td colspan="2">Both Dental Implant Systems are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.</td></tr>
<tr><td>Device</td><td colspan="2">Root form endosseous dental implants and abutments</td></tr>
<tr><td>Range of products</td><td colspan="2">Both Dental Implant Systems include implants, abutments, all required prosthetic components and surgical instrumentation</td></tr>
<tr><td rowspan="5">Design and models</td><td colspan="2">Internal lobe connection</td></tr>
<tr><td colspan="2">Designed to allow clinical flexibility in a single implant system - Time-saving technologies – Intuitive user-friendly design</td></tr>
<tr><td colspan="2">Implants made of Titanium</td></tr>
<tr><td>Unique prosthetic platform</td><td>3 prosthetic platforms</td></tr>
<tr><td>Implant ϕ: 3.4 -5.2 mm</td><td>Implant ϕ: 3.5 -5.0 mm</td></tr>
<tr><td>Implant Lengths: 8-14 mm</td><td>Implant Lengths: 10-15 mm</td></tr>
<tr><td rowspan="2">Surface treatment</td><td colspan="2">Sand blasting roughened surface using calcium phosphate resorbable blast media</td></tr>
<tr><td>Bi Calcium Phosphate (BCP)</td><td>Resorbable Blast Media (RBM)</td></tr>
<tr><td>Sterilization</td><td colspan="2">Single-use - Provided sterile - Gamma radiation</td></tr>
<tr><td>Labeling</td><td colspan="2">Both Dental Implant Systems share same intended use, contra-indications, warnings precautions and potential adverse events</td></tr>
<tr><td>Performance</td><td colspan="2">Both Dental Implant Systems conform to Class II Special Controls Guidance Document:: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff Document issued on May 12, 2004</td></tr>
</table>

Performance data included within this submission demonstrates safety, effectiveness and substantial equivalence.

Revised January 20, 2011

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1. The table under Tab 4, on page 44/45 indicates that your OSSFIT has abutments. This table is incorrect because this implant is a one piece implant. Please submit a revised table.

Not applicable – OSSFIT has been deleted from K101913

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Eric Geneve
CEO
ANTHOGYR SAS
2237 avenue Andre Lasquin
SALLANCHES, FRANCE 74700

MAR 11 2011

Re: K101913
Trade/Device Name: Anthogyr Dental Implant System: Axiom
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 1, 2011
Received: March 7, 2011

Dear Mr. Geneve:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: ANTHOGYR DENTAL IMPLANT SYSTEM: AXIOM

Indications for Use:

ANTHOGYR Dental Implant System AXIOM is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

Prescription Use ✓ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Susan Runo

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

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