ARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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ANTHOGYR SAS
Therese Candau
Regulatory Affairs Engineer
2237 Avenue Andre Lasquin
Sallanches, 74700
FRANCE

June 15, 2017

Re: K161177
Trade/Device Name: Axiom® PX
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 12, 2017
Received: June 13, 2017

Dear Therese Candau:

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 Industry and Consumer Education 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 Industry and Consumer Education 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 -A

Lori A. Wiggins, MPT, CLT
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Division of Anesthesiology,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161177

Device Name
Axiom® PX

Indications for Use *(Describe)*
Anthogyr dental implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures. Anthogyr dental systems are indicated for one-stage or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5
510(K) SUMMARY

510(k) SUMMARY

5.1 SUBMITTER'S CONTACT INFORMATION

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Preparation date: 06/14/2017

5.2 DEVICE

Trade name: AXIOM® PX
Classification name: Endosseous Dental Implant
Class II
Product Code: DZE / NHA
CFR Section: 21CFR 872.3640
Device panel: DENTAL
510(k) Number: K161177

5.3 PREDICATE DEVICE

Primary Predicate Device

K131066, AXIOM® REG manufactured by Anthogyr for implants

Reference Predicate Device

K101913, Anthogyr Dental Implant System: Axiom manufactured by Anthogyr

K992538, Amorphous diamond coated screw manufactured by NobelBiocare for attachment screws

5.4 DEVICE DESCRIPTION

The AXIOM® PX implant system has been designed in order to enhance the functional and aesthetic integration of implant supported restorations.
The file concerns the implants and abutment screws. The prosthetic components and surgical instrumentation are the same as for the AXIOM® REG (see 510(k) K101913 and K131066) and are compatible with Axiom® PX implants.
Implants:
Replacement of a missing root for placement of a dental restoration. The implant is screwed in the upper or lower jaw.
Material: Ti6Al4V-ELI
Surface treatment: BCP®
Dimensions, Ø3.4, length 8, 10, 12, 14, 16, 18 mm
Ø 4.0, length 8, 10, 12, 14, 16, 18 mm
Ø4.6, length 6.5, 8, 10, 12, 14 mm
Ø5.2, length 6.5, 8, 10, 12 mm

Screws:
Screwing the abutment into the implant and the secondary parts into the abutment.
Material: Ti6Al4V-ELI
Surface treatment: DLC
Dimensions: M1.4, length 5, 7.9 mm

5.5 INDICATIONS FOR USE

Anthogyr dental implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures.
Anthogyr dental systems are indicated for one-stage or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading.

5.6 PERFORMANCE TESTING

ANTHOGYR AXIOM® PX conforms 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.

Sterilization validation

Gamma irradiation sterilization was conducted on a representative worst case implant in order to support sterility of the implants, in accordance with ISO 11137 series standards. Sterilization validation was performed on the predicate device (K131066).

Both implants and DLC screws are sold sterile.

Validation of the recommended cleaning and sterilization parameters for end-user sterilized products was conducted according to ISO 17665-1 and ISO 17665-2 to validate DLC screws sterilization when sold non sterile.

Shelf-life validation

The shelf-life has been validated in accordance with ASTM F1980 under accelerated and real-time ageing and supports that the product remains sterile throughout the shelf life. Dye penetration test (ASTM F1929-15), peeling testing, seal strength testing (ASTM F88-15) as well as sterility test were performed.

Biomechanical testing

Static and fatigue testing has been conducted on a representative worst case scenario in air in accordance with ISO 14801 (2007) and Special Controls Guidance Document : Root-form Endosseous Dental Implant and Endosseous Dental Abutments - Guidance for Industry and FDA Staff Document issued on May 12, 2004. The fatigue limit has been compared to the predicate Axiom REG implants fatigue limit (K131066). Surface area analysis, insertion torque testing, and pull-out strength testing has been included in this submission to demonstrate substantial equivalence.

Biocompatibility testing

Biocompatibility assessment has been performed according to ISO 10993 series standards for implants and abutment screws.

Implants:

Chemical characterization (ISO 10993-18:2005 – to determine the type and levels of extractable chemicals present).

Cytotoxicity test (ISO 10993-5:2009 - the cytotoxicity test is used to determine the biological response of mammalian cells in vitro by exposing mouse fibroblast cells after extraction).

Abutment screws:
Chemical characterization (ISO 10993-18:2005)
Cytotoxicity test (ISO 10993-5:2009)
Intracutaneous study (ISO 10993-10:2010 - Intradermal injection of test extracts in the rabbit to evaluate the potential of the material to produce irritation).
Sensitization study (ISO 10993-10:2010 – to assess the contact sensitization potential of the device in the albino guinea pig after a polar and non-polar extraction).

Surface analysis
SEM for the implants as required by FDA guidance class II special controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments.

5.7 TECHNOLOGICAL CHARACTERISTICS

5.7.1 Implants

	Candidate Axiom PX	**Predicate Axiom REG**	**Comparison**
Picture			The thread of the PX implant is different from the REG implant in order to easier the post-extractional placement and low-density bone
Material	Titanium: Ti6Al4V-ELI	Titanium: Ti6Al4V-ELI	Same material for both implants
Indications for use	Anthogyr dental implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures. Anthogyr dental systems are indicated for one-stage or two-stage	Anthogyr dental implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures. The Axiom dental system is indicated for one-stage or two-stage surgery. It is up to the practitioner	The indications for use are the same for both implants. The indications for Axiom REG include both implants and prosthetic parts indications. The Axiom PX indications include only the implants indications as the prosthetic parts are not presented here.

	surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading.	to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading. Prefabricated components are intended for use as accessories to dental implants to support implant-supported restorations.	
Compatible abutments	Axiom REG Aesthetic abutments Axiom REG Standard abutments Axiom REG conical abutments Axiom REG Healing screws	Axiom REG Aesthetic abutments Axiom REG Standard abutments Axiom REG conical abutments Axiom REG Healing screws	Same compatible abutments
Dimensions	Ø3.4 mm; Length 8-18 mm Ø4.0 mm; Length 8-18 mm Ø4.6 mm; Length 6.5-14 mm Ø5.2 mm; Length 6.5-12 mm	Ø3.4 mm; Length: 8-18 mm Ø4.0 mm; Length: 6.5-18 mm Ø4.6 mm; Length: 6.5-14 mm Ø5.2 mm; Length: 6.5-14 mm	The PX implants dimensions available are included in the range of REG implants
Surgical approach	One stage surgery Two stages surgery Immediate loading	One stage surgery Two stages surgery Immediate loading	The surgical approach is the same
Surface treatment	sand blasting BCP + passivation	sand blasting BCP + passivation	Same treatment surface for both implants
Sterilization method	Gamma radiation	Gamma radiation	Same sterilization process for both implants

5.7.2 Abutment screws

	Candidate Axiom PX screw	**Predicate NobelBiocare**	**Comparison**
Material	Titanium: Ti6Al4V-ELI	Titanium: Ti6Al4V-ELI	Both made from same material
Indications for use	Anthogyr dental implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures. Anthogyr dental systems are indicated for one-stage	The Amorphous Diamond Coated Screw is used to retain prosthetic components to dental implants or to other prosthetic components. The amorphous diamond coating will add a greater pre-load to the screw, which in turn help prevent the screw and prosthetic	The indication for the predicate is specific to the Diamond Coated Screw, while the indication for the subject device describes the entire implant system, including the Axiom PX screw.

	or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading.	components from loosening.	
Compatible abutments	Axiom REG Aesthetic abutments Axiom REG Standard abutments Axiom REG conical abutments	Pre-fabricated titanium abutments compatible with NobelActive implants	Each system has its own compatible range
Connection type	Internal conical connection	Internal conical connection	Both internal conical connection
Surface treatment	Diamond Like Carbon	Diamond Like Carbon	Both DLC surface treatment
Sterilization method	Delivered not sterile or sterile with abutment	Delivered not sterile	Anthogyr screw can be delivered sterile. The sterilization method has been validated

5.8 CONCLUSION

ANTHOGYR AXIOM® PX is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function. Non clinical performance testing according to special control demonstrate that ANTHOGYR AXIOM® PX is substantially equivalent to its predicate device.

The mechanical testing shows that the performance of the Axiom PX implants is substantially equivalent to the predicate device.
Based on technological characteristics included in this submission, the Axiom PX implants have been shown to be substantially equivalent to the Axiom REG implants.