K093894

MAR - 3 2010

anthogyr

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

Submitter	ANTHOGYR (Registration number 8020776) 2237, avenue André Lasquin 74700 SALLANCHES FRANCE Phone: 33(0)4 50 58 02 37 Fax: 33(0)4 50 93 78 60 Web : www.anthogyr.com
Contacts	Sabine BRAYETTE (QULITY INGINEER IN CHARGE OF REGULATORY AFFAIRS) sabine.brayette.prod@anthogyr.com
Trade Names	ANTHOGYR « Impulsion » Implantology Contra-angles
Legally marketed predicate devices	Anthogyr Implantology Contra angles K040674
Classification Name	Dental handpiece and accessories
Class	I
Product Code	EFA
CFR section	872.4200
Intended Use	ANTHOGYR's fully autoclavable contra-angles Implantology « Impulsion » are devices intended for a wide range of dental procedures including: Implant surgery such as perforating the bone, tapping and threading procedures

2. INTENDED USE

ANTHOGYR's fully autoclavable contra-angles Implantology « Impulsion » are devices intended for a wide range of dental procedures including:

✓ Implant surgery such as perforating the bone, tapping and threading procedures.

3. DEVICE DESCRIPTION

ANTHOGYR has developed a full range of surgical contra angle intended to be used in implantology. The name of the range is « **Impulsion** » . ANTHOGYR Contra angles design, size and performance conform to NF EN ISO 7785-2 "Dental Handpieces - Part 2: Straight and geared angle handpieces".

4. PERFORMANCE DATA

ANTHOGYR Contra angles & Handpieces conform to the following FDA recognized Consensus standards:

- ✓ ISO 14971 (2001) "Medical devices - Application of risk management to medical devices" (Recognition List Number: 005 Effective Date: 05/04/2001)
- ✓ ISO 15223 (2000) « Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied » (Recognition List Number: 008 Effective Date: 10/29/2003)
- ✓ ISO 13402 (2002) « Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure » (recognized Recognition List Number: 001 Effective Date: 02/19/1998)
- ✓ ISO 7785-2 (1995) "Dental Handpieces - Part 2: Straight and geared angle handpieces" (Recognition List Number: 003 Effective Date: 05/03/1999)
- ✓ ISO 3964 (1982) "Dental Handpieces - Coupling dimensions" (Recognition List Number: 003 Effective Date: 05/03/1999)
- ✓ ISO 7153-1 (1999) « Surgical instruments - Metallic materials - Part 1 : stainless steel » (Recognition List Number: 006 Effective Date: 10/01/2001)

In addition, ANTHOGYR Contra angles & Handpieces conform to the following standards:

- ✓ ISO 13485 (1996) "Medical devices - Particular requirements for the application of the ISO 9001"
- ✓ NF EN ISO 1797-1 (1995) "Dental rotatory instruments - Shanks - Par 1: Shanks made of metal"

- ✓ NF EN ISO 17664 (2004) « Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices »

5. SUBSTANTIAL EQUIVALENCE

The ANTHOGYR « Impulsion » Implantology Contra-angles have the same fundamental scientific technology, operating principle and intended use as predicate devices.

Summary preparation date: December 15, 2009

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

MAR - 3 2010

Ms. Sabine Brayette
Quality Engineer in Charge of Regulatory Affairs
Anthogyr
2237 Avenue André Lasquin
Sallanches
FRANCE 74700

Re: K093894
Trade/Device Name: Anthogyr Contra Angles and Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFA
Dated: January 20, 2010
Received: February 1, 2010

Dear Ms. Brayette:

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" (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,

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 CONTRA ANGLES AND HANDPIECES

- ✓ **Indications for Use:** ANTHOGYR's fully autoclavable contra-angles Implantology « Impulsion » are devices intended for a wide range of dental procedures including:
- ✓ Implant surgery such as perforating the bone, tapping and threading procedures

This range can be used with special accessories like depth stop.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz DDS for Dr. K. P. Mulley
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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