MAR 2 3 2011

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 (QUALITY ENGINEER IN CHARGE OF REGULATORY AFFAIRS) sabine.brayette.prod@anthogyr.com
Trade Name	Anthogyr « Implanteo » implantology and dental surgery motor unit
Legally marketed predicate devices	ANTHOGYR Implanteo (K041279) - ANTHOGYR contra-angle (K090676) BIEN-AIR CHIROPRO L (K092214) - W&H implantMED (K052741)
Classification Name	Dental handpieces and accessories
Class	I
Product Code	EBW
CFR section	872.4200
Intended Use	✓ IMPLANTEO implantology and dental surgery motor unit are indicated to perform dental implant surgery, such as perforating the bone and tapping and threading procedures required before placement of implant prosthetics.

2. INTENDED USE

IMPLANTEO implantology and dental surgery motor unit are indicated to perform dental implant surgery, such as perforating the bone and tapping and threading procedures required before placement of implant prosthetics.

3. DEVICE DESCRIPTION

ANTHOGYR has developed "IMPLANTEO" implantology and dental surgery motor unit intended to perform dental implant surgery which is substantially equivalent to legally marketed and FDA cleared predicate devices.

The ANTHOGYR "IMPLANTEO" implantology and dental surgery motor unit consist of design improvement of non essential characteristics of the device. The ANTHOGYR "IMPLANTEO" implantology and dental surgery motor unit has the same fundamental scientific technology, operating principle and intended use as ANTHOGYR IMPLANTEO (K041279) with ANTHOGYR implantology contra-angle (K090676) or BIEN-AIR CHIROPRO L (K092214) with NSK contra-angle (K970953) or W&H implantMED (K052741) with contra-angle (K080939).

4. PERFORMANCE DATA

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

- ✓ ISO 15223-1 (2007) "Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied" (Recognition number 5-31)
- ✓ IEC 11498 (1997) "Dental Handpieces : Dental low-voltage electrical motors" (Recognition number 4-83)
- ✓ IEC 60601-1 (2005) "Medical Electrical Equipment - Part 1 : General Requirements for safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995" (Recognition number 5-4)
- ✓ IEC 60601-1-2 (2001) "Medical Electrical Equipment - part 1-2 : General Requirements for safety - collateral standard : Electromagnetic Compatibility - Requirements and tests" (Recognition number 5-34)
- ✓ ISO 7785-2 (1998) "Dental Handpieces - Part 2: Straight and geared angle handpieces" (Recognition number 4-76)
- ✓ ISO 3964 (1982) "Dental Handpieces - Coupling dimensions" (Recognition List Number: 003 Effective Date: 05/03/1999)

In addition, ANTHOGYR « IMPLANTEO » implantology and dental surgery motor unit and ANTHOGYR Contra angles conform to the following standards:

- ✓ ISO 14971 (2007) "Medical devices – Application of risk management to medical devices" (Recognition number : 5-40)
- ✓ 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 « IMPLANTEO » implantology and dental surgery motor unit have the same fundamental scientific technology, operating principle and intended use as predicate devices.

Summary preparation date: February 1, 2011

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

Ms. Brayette Sabine
Quality Engineer
Anthogyr ASA
2237, Avenue Andre Lasquin
Sallanches, France 74700

MAR 2 3 2011

Re: K102241
Trade/Device Name: ANTHOGYR "IMPLANTEO" IMPLANTOLOGY AND DENTAL SURGERY MOTOR UNIT
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: March 14, 2011
Received: March 18, 2011

Dear Ms. Sabine:

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,

for

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

anthogyr

Indications for Use

K102241

510(k) Number (if known): _____

Device Name: ANTHOGYR "IMPLANTEO" IMPLANTOLOGY AND DENTAL SURGERY MOTOR UNIT

Indications for Use:

ANTHOGYR's IMPLANTEO implantology and dental surgery motor unit are indicated to perform dental implant surgery, such as perforating the bone and tapping and threading procedures required before placement of implant prosthetics.

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)

Susan Runner

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

510(k) Number: K102241