OCT - 7 2011

anthogyr

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

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Trade Names	MontBlanc Surgical contra-angle handpiece and straight handpiece
Legally marketed predicate devices	ANTHOGYR Contra-angle and Handpiece (K040674) ANTHOGYR MontBlanc Contra-angle (K090676) WH Surgical contra-angle Handpieces (K011061) WH Surgical contra-angle and straight handpiece (K080939)
Classification Name	Dental handpieces and accessories
Class	I
Product Code	EGS
CFR section	872.4200
Intended Use	Indications are very widespread in the field of implantology and surgery. The mentioned handpieces have been developed especially for the following applications : - MontBlanc Surgical contra-angle handpiece : for e.g. hemisection, wisdom tooth extraction. - MontBlanc Surgical straight handpiece : for e.g. application in the area of the front teeth, root tip resection, bone removal, osteotomy on the upper and lower

	jaw, preprosthetic surgical osteoplasty, sequestrum removal, fenestration on the alveolar appendix, apical ventilation, bone osteoplasty, bone smoothing.

2. INTENDED USE

Indications are very widespread in the field of implantology and surgery. The mentioned handpieces have been developed especially for the following applications :

- MontBlanc Surgical contra-angle handpiece : for e.g. hemisection, wisdom tooth extraction.
- MontBlanc Surgical straight handpiece : for e.g. application in the area of the front teeth, root tip resection, bone removal, osteotomy on the upper and lower jaw, preprosthetic surgical osteoplasty, sequestrum removal, fenestration on the alveolar appendix, apical ventilation, bone osteoplasty, bone smoothing.

3. DEVICE DESCRIPTION

Reference	Contra-angle handpiece			Straight handpiece	
	12200X	12200XL	12200XLED	12400X	12400XLED
Reduction / multiplication rate	1 : 3			1 :1	
Colour code	Orange			blue	
Weight (g)	98			125	
Light	NO	OPTIC FIBER	LED	NO	LED
Motor connection standard	ISO 3964	ISO 3964 (type Intra-Matic Lux)	ISO 3964 (type Intra-Matic Lux with anthogyr connexion system)	ISO 3964	ISO 3964 (type Intra-Matic Lux with anthogyr connexion system)
Maximum motor speed (rpm)	40 000				
Tool type according to NF EN ISO 1797-1	Type 3			Type 1 ou 2	

Reference	Contra-angle handpiece			Straight handpiece	
	12200X	12200XL	12200XLED	12400X	12400XLED
Diameter of tools (mm) according to NF EN ISO 1797-1	1.60			2.35	
Maximum length recommended by Anthogyr (mm)	25 *			65 *	
Maximum diameter of the active part of the tool recommended by Anthogyr (mm)	2 *			10 *	
Water spray output according to ISO 7785-2 (ml/min)	> 50				

- (*) Suggested values. If using longer and wider diameter rotary instruments, the user is responsible for the correct choice of the operating conditions to prevent any risk to the patient or to a third person.

4. PERFORMANCE DATA

MontBlanc Surgical contra-angle handpiece and straight handpiece 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)
- ✓ 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)
- ✓ ISO 7405 Second edition 2008-12-15 "Dentistry – Evaluation of biocompatibility of medical devices used in dentistry" (Recognition List Number : 022)

In addition, MontBlanc Surgical contra-angle handpiece and straight handpiece 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 MontBlanc Surgical contra-angle handpiece have the same fundamental scientific technology, operating principle as ANTHOGYR Contra-angles (K090676).

The ANTHOGYR MontBlanc Surgical contra-angle handpiece and straight handpiece have the same fundamental scientific technology, operating principle and intended use as W&H contra-angle handpiece and straight handpiece legally marketed (K011061).

The ANTHOGYR MontBlanc Surgical straight handpiece have the same fundamental scientific technology as ANTHOGYR Contra-angles (K040674).

MontBlanc Surgical contra-angle handpiece and straight handpiece have the same fundamental scientific technology, operating principle and intended use as predicate devices.

Summary preparation date: September, 15th 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. Sabine Brayette
Quality Engineer In Charge Of Regulatory Affairs
Anthogyr Sas
2237 Avenue Andre Lasquin
Sallanches
France 74700

OCT - 7 2011

Re: K111532
Trade/Device Name: MontBlanc Surgical Contra-Angle Handpiece and Straight Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: September 28, 2011
Received: September 30, 2011

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" (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

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Indications for Use

510(k) Number (if known): K111532

Device Name: MontBlanc Surgical contra-angle handpiece and straight handpiece

Indications for Use:

Indications are very widespread in the field of implantology and surgery. The mentioned handpieces have been developed especially for the following applications :

- MontBlanc Surgical contra-angle handpiece : for e.g. hemisection, wisdom tooth extraction.
- MontBlanc Surgical straight handpiece : for e.g. application in the area of the front teeth, root tip resection, bone removal, osteotomy on the upper and lower jaw, preprosthetic surgical osteoplasty, sequestrum removal, fenestration on the alveolar appendix, apical ventilation, bone osteoplasty, bone smoothing.

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)

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

510(k) Number: K111532