K 041279

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SEP 2 3 2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

Submitter	ANTHOGYR (Registration number 8020776) 164 rue des trois lacs 74700 SALLANCHES FRANCE Phone: 33(0)4 50 58 02 37 Fax: 33(0)4 50 93 78 60
Contacts	Eric GENEVE (RD Manager) e.geneve.rd@anthogyr.com Regulatory Affairs: Idée Consulting (Dr Isabelle DRUBAIX) idrubaix@nordnet.fr
Common Name	Surgical motor for implantology
Classification Name	Dental Handpieces and accessories
Trade Name	IMPLANTEO
Class	I
Product Code	EKX
CFR section	872.4200
Device panel	DENTAL

2. DEVICE DESCRIPTION

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

IMPLANTEO kit includes: Control unit, Peristaltic pump, Motor, Motor holder, Control pedal, Calibration module, Bag carrier

Four adjustable parameters are displayed on a large size screen : Speed which adjustment takes into account the reduction value used, Torque, Pump flow rate and Contra angle reduction ratio

In order to cover all the possible uses of the motor, up to 3 different protocols can be programmed. Each protocol allows for implant fitting in 4 sequences: drilling, reaming, tapping and screwing.

3. INTENDED USE

IMPLANTEO dental unit is indicated to perform dental implant surgery, such as perforating the bone and taping and threading procedures required before placement of implant prosthetics.

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4. PERFORMANCE DATA

IMPLANTEO conforms to the following voluntary FDA recognized Consensus standards:

- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- ISO 11498 (1997) Dental Handpieces: Dental Low Voltage Electrical Motors
- ISO 13402 (1995) « Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure »
- ISO 15223 (2000) « Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied »
- NF EN ISO 7494 (1997) Dental units
- NF EN ISO 7153-1 (2000) Surgical instruments - Metallic materials - Part 1 : stainless steel
- EN 1441 (1997) "Medical devices – Risk management"

5 SUBSTANTIAL EQUIVALENCE

Predicate devices:

K033597 - ATR 5000 Implant system – Advanced Technology Research

K030163 –VCT Versatile Control Technology Model AEU -925 – Aseptico

IMPLANTEO is substantially equivalent to these predicate devices in terms of intended use, material, design and function.

Summary preparation date: April 30, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2004

Mr. Eric Geneve
R & D Manager
ANTHOGYR
164 Rue Des Trois Lacs
74700 Sallanches
FRANCE

Re: K041279
Trade/Device Name: IMPLANTEO Implantology Motor
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: August 3, 2004
Received: August 3, 2004

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
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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510(k) Number (if known): K041279

Device Name: IMPLANTEO Implantology Motor

Indications for Use: IMPLANTEO motor is indicated to perform dental implant surgery, such as perforating the bone and taping and threading procedures required before placement of implant prosthetics.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use X **or** **Over-the-Counter Use**

(PER 21 CFR 801.109)

Susan Runner

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

510(k) Number K041279

(Optional Format 1-2-96)