K040671

DEC 14 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	CARTRIDGE SYRINGE
Classification Name	CARTRIDGE SYRINGE
Class	II
Product Code	EJI
CFR section	872.6770
Device panel	DENTAL

2. DEVICE DESCRIPTION

ANTHOGYR has developed cartridge syringes which are substantially equivalent to legally marketed and FDA cleared predicate devices.

Intraligamental syringes

ERGOJECT and MINIJECT are syringes for every kind of anesthesia, especially intraligamental and intraseptal that requires high pressure. ANTHOGYR intraligamental syringes feature an ergonomic handle constructed of thermoplastic resin and have a leverage factor of three (ERGOJECT) or five (MINIJECT) to make it easier to use and an anti-reverse, non-ratcheting mechanism that prevents the plunger from slipping during injection.

Aspirating dental cartridge syringes

ANTHOGYR developed a full range of dental cartridge syringes including: Self aspirating syringe (ISO 9997 Type 2b - Aspiration under the effect of strength produced by the bending of a diaphragm in the cartridge), Aspirating syringe (ISO 9997 Type 2a - Aspiration under the effect of strength produced by the receding of the button in relation to the needle) and dental syringes without aspiration (ISO 9997 Type 1).

3. INTENDED USE

ANTHOGYR cartridge syringes are devices intended to inject anesthetic solutions in the oral cavity.

4. PERFORMANCE DATA

ANTHOGYR cartridge dental syringes conform to NF EN ISO 9997 (2000) "Dental cartridge syringes" and to ISO 13402 (1995) « Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure »

5. SUBSTANTIAL EQUIVALENCE

ANTHOGYR Devices	Predicate devices
Ergoject / Minijject intraligamental syringes	Minijject (Spartan Ultrasonics) K991888
Self aspirating Stainless steel anesthetic syringe	Aspijject (Ronvig Instruments) K002168
Stainless steel and chrome plated anesthetic syringes	Numerous devices currently on market (Cartridge Syringes - Septodont Inc, Ranfac, Cook Waite Kodak, Miltex ...)

ANTHOGYR Devices are substantially equivalent to these predicate devices in terms of intended use, material, design and function.

Summary preparation date: February 23, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2004

Mr. Eric Geneve
Anthrogyr
164 Rue De Trois Lacs
Sallanches,
FRANCE, F74700

Re: K040671
Trade/Device Name: ANTHOGYR CARTRIDGE SYRINGES
Regulation Number: 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: II
Product Code: EJI
Dated: October 18, 2004
Received: October 18, 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.

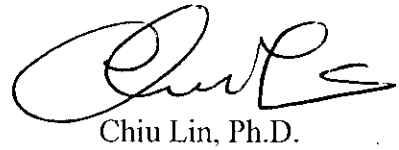
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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

K040671

anthogyr

510(k) Number (if known): K040671

Device Name: ANTHOGYR CARTRIDGE SYRINGES

Indications for Use: ANTHOGYR cartridge syringes are devices intended to inject anesthetic solutions in the oral cavity.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

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

(PER 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

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

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