K053578

I. 510 (k) SUMMARY

Submitter information:

JUL 14 2006

SCORPION
ZA La Novialle
3, rue de la Lagune
63670 LA ROCHE BLANCHE
FRANCE
Tel: + 33 473 782 087
Fax: +33 473 782 087

Contact person: Stéphane GIGAULT, manager

Date prepared: 13 December 2005

Device name:

Trade name: Scorpion ultrasonic scaling inserts
Common name: Ultrasonic scaling insert
Classification name: Ultrasonic scaler

Legally marketed devices to witch equivalence is claimed:

- SATELEC #1 insert, accessory of SP NEWTRON module (K033764) from SATELEC

- EMS "A" insert, accessory of EMS KERMIT® (K992504) from EMS

- Sapphire Plus® Tips (K960889) from SAN DIEGO Swiss Machining,

The product and its intended use:

The Scorpion ultrasonic scaling inserts are used by dental professionals during dental cleaning procedures to remove supragingival calculus deposits from teeth by application of ultrasonic vibration.

Scorpion manufactures several kinds of ultrasonic scaling inserts adaptable on different ultrasonic scalers.

This notification concerns two inserts adaptable on piezo-electric scalers as follows:

- BSA scaling insert, adaptable on SATELEC scalers handpieces.

- BEM scaling insert, adaptable on EMS scalers handpieces.

The Scorpion ultrasonic inserts have essentially the same internal design as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2006

Scorpion
C/O Mr. Daniel Kamm
Kamm & Associates
333 Milford Road
Deerfield, Illinois 60015

Re: K053578
Trade/Device Name: Scorpion Ultrasonic Scaling Inserts
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: June 23, 2006
Received: July 12, 2006

Dear Mr. Kamm:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

K053578

Indications for Use

510(k) Number (if known):

Device Name: Scorpion ultrasonic scaling inserts.

Indications For Use: Scorpion ultrasonic scaling inserts are used by dental professionals during dental cleaning procedures to remove supragingival calculus deposits from the teeth.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mackey for HSR

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...(k) Number: K053578

Scorpion - 3, rue de la Lagune - ZA la Novialle - 63670 LA ROCHE BLANCHE - FRANCE
Tel/Fax +33 (0)4 73 78 20 87
ISO 9001 CE ISO 13485