K071965

1 of 2

13. SMDA Summary of Safety and Effectiveness – "510(k) Summary"

A. Submitter Information

SATELEC
Z.I. du Phare, BP 30216
17, Avenue Gustave Eiffel
33708 Merignac Cedex
FRANCE

Telephone: 011 33 556 34 0607
Fax: 011 33 556 34 9292

Contact Person: Steve Salesky
SATELEC
c/o Acteon, Inc.
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054
Telephone: 800 289-6367 Ext. 40
Fax: 856 222-4726
E-mail: steve.salesky@us.acteongroup.com

SEP 10 2007

Date Prepared: July 12, 2007

B. Device Identification

Common Usual Name: Dental Handpiece

Proprietary Name: i-Surge

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
Suni Max	Satelec	K000049	April 4, 2000

The Satelec i-Surge is substantially equivalent to the predicate device by Satelec, Suni Max (K000049) previously cleared by the FDA and currently marketed.

D. Device Description

The Satelec i-Surge is intended to be used by qualified dental practitioners as an electric micro-motor handpiece with straight, right or contra-angle attachment for oral dental surgical procedures including implantology, endodontia, periodontology, and dental maintenance.

Functions and settings are selected and adjusted by the footswitch and / or the front panel keyboard on the control unit.

E. Substantial Equivalence

Both the Satelec i-Surge and the predicate device, Satelec Suni Max (K000049) are intended to be used by qualified dental practitioners as an electric micro-motor handpiece with straight, right or contra-angle for oral dental surgical procedures including implantology, endodontia, periodontology, and dental maintenance. Differences that exist between the devices relating to technical specifications, performances, and intended use are minor and do not affect the safety and effectiveness of the i-Surge.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 2007

SATELEC
C/O Mr. Steve Salesky
Quality Manager
ACTEON, Incorporated
124 Gaither Drive, Suite 140
Mount Laurel, New Jersey 08054

Re: K071965
Trade/Device Name: i-Surge
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: July 12, 2007
Received: July 16, 2007

Dear Mr. Salesky:

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/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

1 of 1

Indications for Use

K071965

510(k) Number: _____

Device Name: **i-Surge**

Indications for Use:

The Satelec i-Surge is intended to be used by qualified dental practitioners as an electric micro-motor handpiece with a straight, right or contra-angle attachment for oral dental surgical procedures including implantology, endodontia, periodontology, and dental maintenance.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number: K071965