8. Cleaning, Disinfecting, and Sterilization:

Unit casing can be decontaminated with dental disinfectant wipes.

Sterile tubing for irrigation is ethylene oxide (EO) sterilized and is for single use only.

Refer to specific user manuals for cleaning, disinfecting, and sterilizing the handpieces and cords used with the dental operative unit.

9. 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
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NOV 1 9 2007

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

Date Prepared: July 23, 2007

B. Device Identification

Common Usual Name: Dental operative unit and accessories

Proprietary Name: Implant Center

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
Cocoon Hygienist	Satelec	K040529	August 19, 2004

The Satelec Implant Center is substantially equivalent to the predicate device by Satelec, the Cocoon Hygienist (K040529) previously cleared by the FDA and currently marketed.

D. Device Description

The Satelec Implant Center is a dental operative unit that supplies utilities to and serves as a base for dental tools and accessories for use by qualified dental practitioners.

E. Substantial Equivalence

The Implant Center and the predicate device, Cocoon Hygienist (K040529) are both dental operative units that supply utilities to and serve as a base for dental tools and accessories for use by qualified dental practitioners. 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 Implant Center.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2007

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

Re: K072030
Trade/Device Name: Implant Center
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: November 12, 2007
Received: November 14, 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,

Neil R. P. Ogden for

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

Indications for Use

510(k) Number: K072030

Device Name: **Implant Center**

Indications for Use:

The intended use of the Satelec Implant Center is to supply utilities to and serve as a base for dental tools and accessories for use by qualified dental practitioners.

Prescription Use ___X___ (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)

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

510(k) Number: K072030