AUG 1 9 2004

K040529

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

A. Submitter Information

SATELEC
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Contact Person: Pascal Dupeyron
Regulatory Affairs

Date Prepared: February 25, 2004

B. Device Identification

Common/Usual Name: Delivery System
Proprietary Name: Cocoon Hygienist

C. Identification of Predicate Devices

The Cocoon Hygienist is substantially equivalent to the predicate device by Boyd Industries, Inc., Boyd Delivery Units (K020833) previously cleared by FDA and currently marketed.

D. Device Description

The Cocoon Hygienist is a dental operative unit that provides the dentist with primary requirements for dental operations. The delivery system is designed to be used as an interface device to connect the dental operating hand instruments to the appropriate supply utilities such as air, water suction, drain, and electricity. The unit is supplied with controls that allow the dentist, dental hygienist, or operator to set the water flow to the hand pieces. The water flow of the syringe, directly connected to main water supply, depends on the input water pressure. The output air pressure is preset in the unit.

The intended use of the Satelec Cocoon Hygienist is to supply utilities to and serve as a base for dental tools and accessories for the dental professional.

E. Substantial Equivalence:

The technical characteristics of the Cocoon Hygienist are almost identical to those of the Boyd Industries Inc., Dental Operative Units (K020833). Differences that exist between the systems relating to technical specifications, materials, physical appearance, and control systems are minor and do not affect the relative safety or effectiveness of the Cocoon Hygienist.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 9 2004

Satelec
C/O Dr. Jean-Luc Boulnois
President
Interactive Consulting, Incorporated
70 Walnut Street
Wellesley, Massachusetts 02481

Re: K040529
Trade/Device Name: Cocoon® Hygienist
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: August 10, 2004
Received: August 11, 2004

Dear Dr. Boulnois:

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

510(k) Number (if known): K040529

Device Name: **Cocoon® Hygienist**

Indications for Use:

The Cocoon® Hygienist is a dental operative unit intended to supply utilities to and serve as a base for dental tools and accessories for use by dental professionals.

Please refer to the attached listing for a complete description.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K040529

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)