

K972026

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

JUL - 9 1997

A. Submitter Information

SATELEC  
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Avenue Gustave Eiffel  
33708 Merignac Cedex  
FRANCE

Telephone: 011-33-5-56-34-06-07

Contact Person: Pascal Dupeyron  
Regulatory Affairs

Date Prepared: May 28, 1997

B. Device Identification

Common/Usual Name	Piezoelectric Ultrasonic Scaling Generator
Proprietary Name:	SP 4055 and SP 4055 LUX Modules

C. Identification of Predicate Device(s)

The SP 4055 and SP 4055 LUX Modules are substantially equivalent to its predicate device, SUPRASSON P5 Booster (K961158) previously cleared and currently marketed.

D. Device Description

The SP 4055 and SP 4055 LUX modules are sub-assemblies of the SUPPRASON P5 Booster Piezoelectric Ultrasonic Scaling Generator which received 510(k) clearance for dental applications (K961158) on May 23, 1996. The SP 4055 and SP 4055 LUX Modules maintain all the functions and the main components of the SUPRASSON P5 Booster, but are stand-alone sub-assemblies manufactured by SATELEC, all with the same components and materials used in the manufacture of the original SUPRASSON P5 Booster product, which can be used in standard dental units. The intended use, technical performance, and clinical indications are identical to those of their predicate device, the SUPRASSON P5 Booster (K961158).

The SP 4055 and SP 4055 LUX modules are multi-purpose ultrasonic generators to be marketed as modular sub-assemblies to manufacturers of dental units. Each module is shipped with three standard tips, 1, 2, and 10P. The SP 4055 and SP 4055 LUX are comprised of 3 setting ranges:

- scaling, prosthesis removal, amalgam plugging,
- ultrasonic endodontic treatment, and
- ultrasonic periodontal treatment.

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As the ultrasonic waves are produced by piezoelectricity, the SP 4055 and SP 4055 LUX module handpieces give off very little heat, making it possible for surgeons to perform both periodontal work (subgingival work at low power, where the absence of overheating is vital), as well as loosening (requiring high power, but without the unpleasant side-effect of a hot handpiece).

With the activation of a simple spray, the system ensures efficient cavitation and maximum operating power.

The electronics automatic control system has the capability to adjust power instantaneously in function of the resistance encountered by the insert, and varies handpiece and tips frequency so as to optimize power output.

The SP 4055 and SP 4055 LUX Modules, similar to their predicate device, SUPRASSON P5 Booster (K961158), operate from the action of cavitation, following the propagation of ultrasounds in a frequency spectrum comprised between 27 and 35 kHz.

E. Substantial Equivalence

The technical characteristics of the SP 4055 and SP 4055 LUX Modules are almost identical to those of the Satelec SUPRASSON P-5 Booster. Differences that exist between these devices relating to technical specifications, materials, physical appearance, and control systems do not affect the relative safety or effectiveness of the SP 4055 and SP 4055 LUX Modules relative to its predicate.

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The SP 4055 and SP 4055 LUX Modules are intended to provide overall prophylaxis and preservation of soft and hard tissue during the 3 standard dental treatments; Scaling, Periodontics, and Endodontics.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Jacqueline E. Masse  
Sr. Consultant  
Satelec  
C/O Interactive Consulting, Incorporated  
70 Walnut Street  
Wellesley, Massachusetts 02181

JUL - 9 1997

Re: K972026  
Trade Name: SP4044 & SP4055 Lux Modules  
Regulatory Class: II  
Product Code: ELC  
Dated: May 28, 1997  
Received: June 2, 1997

Dear Ms. Masse:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

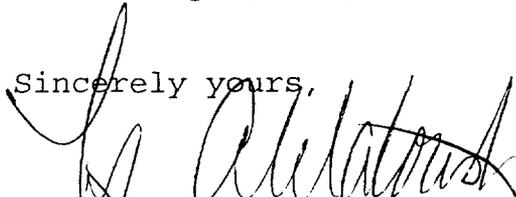
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: **SP 4055 and SP 4055 LUX Modules**

Indications For Use:

**Scaling  
Endodontics  
Periodontics**

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 Dental, Infection Control,  
and General Hospital Devices**

510(k) Number                     K972026                    

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

INDICATIONS FOR USE  
SATELEC SP 4055 AND SP 4055 LUX MODULES

**Scaling:**

- Interdental junction treatment
- Tooth neck and subgingival treatment
- Treatment of large deposits
- Treatment of coatings and tobacco stains
- Treatment of periodontal pockets
- Interproximal treatment
- Retro Surgery
- Plugging
  - Amalgam plugging
- Loosening
  - Prosthesis Loosening (crown, pivot loosening)
- Inlay/Onlay Condensation:
  - Finish of inlay/onlay restorations

**Endodontia:**

- Canal preparation
- Canal cleaning
- Canal filling
- Treatment resumption
- Prosthesis:
  - Preparing in luted denture
  - Surface smoothing after burring
- Micro Retro Surgery
- Gutta Condensation:
  - Treatment resumption on gutta percha
  - Post loosening
  - Silver cone loosening
  - Gutta percha condensation

**Periodontia:**

- Root planing
- Initial therapy
- Treatment of periodontal pockets
- Treatment of furcations
- Maintenance therapy