K131997

Section 006 – 510(k) Summary (SMDA Requirements)
Additional Information – September 17, 2013

This Summary of Safety And Effectiveness is submitted in accordance with 21 CFR 807.92.c.

01 – Administrative Information

01- a. Type of 510(k) submission:

These documents constitute a Traditional 510(k) Submission.

NOV 2 6 2013

01- b. Submission date: June 24, 2013

01-c. 510(k) Submitter:

SATELEC
17, Avenue Gustave Eiffel
BP 30216
33708 Merignac Cedex
France
Telephone: 011-33-556-340-607
Fax: 011-33-556-349-292
E-Mail: philippe.girard@acteongroup.com

01-d. Contact Person:

Rick Rosati
SATELEC
c/o ACTEON, Inc.
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054
Telephone: 800-289-6367 Ext. 390
Fax: 856-222-4726
E-Mail: rick.rosati@us.acteongroup.com

01- e. Establishment Registration Number: 8044015

02 – Device Information

02-a. Trade Name of Device:	NEWTRON BOOSTER
02-b. Common Name of Device:	Ultrasonic Scaler
02-c. Classification Regulation:	21 CFR 872.4850
02-d. Medical Device Class:	II
02-e. Panel:	Dental
02-f. Product Code:	ELC

ISO 13485

SATELEC ACTEON

SATELEC • A company of ACTEON Group
17 av. Gustave Eiffel • BP 30216 • 33708 MERIGNAC cedex • FRANCE
Tel • 33 (0) 556 34 06 07 • Fax • 33 (0) 556 34 92 92
E-mail: satelec@acteongroup.com • www.acteongroup.com
Société pour la Conception des Applications des Techniques Electroniques • S.A.S. au capital de 1 309 548 €
R.C. Bordeaux B 782 016 240 • N° intracommunautaire FR 39 782 016 240

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03 – Identification of Legally Marketed Predicate(s)

The Substantial Equivalence (SE) of the Satelec New Device is based on the Predicate Devices identified in the Table 01.

Table 01 – Identification of Legally Marketed Predicate Devices

Trade Name	Manufacturer	Product Code	510(k) number	Date Cleared
SUPRASSON P5 NEWTRON	SATELEC	ELC	K050895	April 20, 2005
ProUltra Piezo Ultrasonic	SATELEC	ELC	K113430	February 23, 2012

04 – Description of the Device

The Satelec New Device is a Dental Ultrasonic Generator. The Satelec New Device uses Piezoelectric Technology.The Satelec New Device uses a Satelec Dental Piezoelectric Handpiece (NEWTRON SLIM). In option, the Satelec New Device can use the same Handpiece as the Predicate Device SUPRASSON P5 NEWTRON (K050895, cleared April 20, 2005).

The Satelec New Device is designed to be used with Satelec Dental Tips previously cleared with Predicate Devices (K050895, cleared April 20, 2005 and K113430, cleared February 23, 2012) or other new Satelec Dental Tips.

05 – Intended Use

The medical device is used in association with a dental ultrasound handpiece to which an ultrasound instrument is attached. It is designed for the treatment of scaling (prophylaxis), periodontics, endodontics and prosthesis (preservation and restoration dentistry).

06 – Technological characteristics of the Device compared to the Predicate Devices

Technological characteristics of the Satelec New Device are the same as the Predicate Device.

Technological Perspective:
The Satelec New Device and the Predicate Devices use the same technology (Piezoelectricity Technology).

Material perspective:
The Satelec New Device and the Predicate Devices are very similar because the casings are made in self-extinguishing material (UL94V-0).

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SATELEC • A company of ACTEON Group
17 av. Gustave Eiffel • BP 30216 • 33708 MERIGNAC cedex • FRANCE
Tel + 33 (0) 556 34 06 07 • Fax + 33 (0) 556 34 92 92
E-mail: satelec@acteongroup.com • www.acteongroup.com
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Design perspective:

The Satelec New Device and the Predicate Devices use:

- The same Principle of User interface.
- The same Dental Ultrasonic Handpiece (Satelec NEWTRON Handpiece) and / or a derivated Dental Ultrasonic Handpiece (Satelec NEWTRON SLIM Handpiece).

Energy source perspective:

The Satelec New Device and the Predicate Devices:

- Use the same input energy source (Electric Power Supply).
- Deliver the same output energy source (ultrasonic micro-vibration).
- Deliver the same Handpiece Current Values.
- Deliver a similar irrigation Flow values.

07 – Determination of substantial equivalence

The Satelec New Device Indications for Use is similar to the Satelec Predicate Devices. The Satelec New Device is the same as the Satelec Predicate Devices in terms of functioning principle.

The Satelec New Device uses a Satelec NEWTRON SLIM Dental Piezoelectric Handpiece. The Satelec NEWTRON SLIM Dental Piezoelectric Handpiece is based on the Satelec Predicate Devices SUPRASSON P5 NEWTRON (K050895, cleared April 20, 2005) and Satelec ProUltra Piezo Ultrasonic (K113430, cleared February 23, 2012) (same materials, same Piezoelectric Transducters). Also, the Satelec New Device can be used with Satelec NEWTRON Handpiece employed with SUPRASSON P5 NEWTRON (K050895, cleared April 20, 2005)

From external structure perspective, the Satelec New Device and Predicate Devices are very similar because the casings are made in self-extinguishing material (UL94-V0). Also, Satelec New Device and Satelec Predicate Devices use a single function footswitch.

Moreover, the materials in contact to the patient are the same.

08 – Conclusion

The Satelec New Device is the same as the identified Predicate Devices in terms of Indication For Use.
Because of the used technologies, characteristics and performances are similar to the Satelec Predicate Devices, the characteristics of the Satelec New Device do not affect the Safety of the patients or of the operator. Moreover, the Effectiveness is the same as of the Predicate Devices.

There is no doubt that the Satelec New Device is Substantially Equivalent (SE) to the Satelec ProUltra Piezo Ultrasonic (K113430, cleared February 23, 2012) and Satelec SUPRASSON P5 NEWTRON (K050895, cleared April 20, 2005).

End of Section

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SATELEC ACTEON

SATELEC • A company of ACTEON Group
17 av. Gustave Eiffel • BP 30216 • 33708 MERIGNAC cedex • FRANCE
Tel • 33 (0) 556 34 06 07 • Fax • 33 (0) 556 34 92 92
E-mail: satelec@acteongroup.com • www.acteongroup.com
Société pour la Conception des Applications des Techniques Electroniques • S.A.S. au capital de 1 309 548 €
R.C. Bordeaux B 782 016 240 • N° Intracommunautaire FR 39 782 016 240

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17 av. Gustave Eiffel • BP 30216 • 33708 MERIGNAC cedex • FRANCE
Tel + 33 (0) 556 34 06 07 • Fax + 33 (0) 556 34 92 92
E-mail: satelec@acteongroup.com • www.acteongroup.com
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R.C. Bordeaux B 782 016 240 • N° intracommunautaire FR 39 782 016 240

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Satelec-Acteon Group
Mr. Rick Rosati
Quality Manager
C/O ACETON, Incorporated
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054

Re: K131997
Trade/Device Name: NEWTRON BOOSTER
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: November 1, 2013
Received: November 4, 2013

Dear Mr. Rosati:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

for

Erin Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 005 – Indication for Use
Additional Information – September 17, 2013

Indications for Use

510(k) Number (if known): K131997

Device Name: NEWTRON BOOSTER

Indications for Use:

The medical device is used in association with a dental ultrasound handpiece to which an ultrasound instrument is attached. It is designed for the treatment of scaling (prophylaxis), periodontics, endodontics and prosthesis (preservation and restoration dentistry).

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

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Kwame O. Ulmer -S
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Concurrence of CDRH, Office of Device Evaluation (ODE)