K11 0379

DEC - 8 2011

510(k) Pre-Market Notification for AIR-N-GO By SATELEC

EXHIBIT "A"

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

A. Submitter Information

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Date prepared: March 9, 2011

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B. Device Identification

Common Usual Name: Dental Handpiece and Accessories

Proprietary Name: AIR-N-GO

Classification: Class I device (per 21 CFR § 872.4200)

C. Identification of the Predicate Devices

	Predicate 1	Predicate 2	Predicate 3
Device name	EMS AIR-FLOW handy PERIO	EMS AIR-FLOW handy 2	EMS AIR-FLOW MASTER
Sponsor	E.M.S ELECTRO MEDICAL SYSTEMS SA	E.M.S ELECTRO MEDICAL SYSTEMS SA	E.M.S ELECTRO MEDICAL SYSTEMS SA
K number	K092289	K022119	K082791

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D. Device Description

The AIR-N-GO is a dental handpiece intended for the projection of a mixture of air, water and dental powder on the surface of teeth. It is supplied on air and water provided by a dental operative unit. The equipment is connected to a standard turbine connection available on the dental operative units.

The AIR-N-GO can be used with two different nozzles. A SUPRA nozzle is dedicated for the Supra-gingival dental applications whereas a PERIO nozzle is dedicated for the sub-gingival dental applications. The used nozzle is fixed on the front of the device by screwing. The AIR-N-GO can be used with two different heads. The head is available in two lengths according to ergonomics considerations. A front plastic body is the part of the medical device held in the hand of the user during the clinical act. Metallic tubing is used for the conduction of the mixture of air / dental powder and of the water.

A rear body is intended to receive the turbine connector. The rear body can rotate around the metallic tubing. This principle allows the orientation of the nozzle by rotation. The AIR-N-GO can be used with two different tanks. The mixture of the dental powder and the air is realized inside the tank. Tanks are equipped with a bayonet system for a quick change. A blue tank is dedicated for the supra-gingival dental applications. A green tank is dedicated for the sub-gingival dental applications. A tank lid is equipped with a powder stop system which permits to use the device as an air / water syringe. The AIR-N-GO is equipped with a turbine connector according to the model of dental operative unit used by the practitioner.

E. Indications for Use

The AIR-N-GO by SATELEC in supra-gingival configuration is intended for use in the polishing and cleaning of teeth by the projection of a mixture of dental powder, air, water on teeth surfaces. The device can remove soft deposits and areas of discoloration and can be used to prepare teeth for conventional dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers... The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances.

The AIR-N-GO by SATELEC in sub-gingival configuration (with PERIO kit) is intended for patients suffering from periodontitis and peri-implantitis and it is indicated for the non-surgical removal of sub-gingival plaque in pockets up to 5 mm after an initial periodontal treatment.

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F. Substantial Equivalence

The AIR-N-GO is the same as the EMS AIR-FLOW handy PERIO (K092289) predicate device in terms of principle. Both systems consist of a dental handpiece intended for the projection of a mixture of air, water and dental powder on the surface of teeth in sub-gingival dental applications. Also, both systems are composed of a tank, and lid tank and PERIO Nozzle. Both systems are connected to dental operative units with a turbine connector.

The AIR-N-GO is the same principle as the EMS AIR-FLOW handy 2 (K022119) predicate device in terms of principle. Both systems consist of a dental handpiece intended for the projection of a mixture of air, water and dental powder on the surface of teeth in supra-gingival dental application. Also, both systems are composed of a tank, and lid tank and 90° and 120° SUPRA Nozzle. Both systems are connected to dental operative units with a turbine connector.

The AIR-N-GO is the same principle as the EMS AIR-FLOW MASTER (K082791) predicate device in terms of principle. Both systems consist of a dental handpiece intended for the projection of a mixture of air, water and dental powder on the surface of teeth in supra-gingival dental application and sub-gingival dental applications. Both systems can be used for supra-gingival dental application and sub-gingival dental applications.

Evaluation tests have demonstrated the substantial equivalence of the AIR-N-GO device and these selected predicates for supra-gingival and sub-gingival applications. The effectiveness, the safety and the adverse effects have been evaluated during the tests. The results obtained are quite similar between each system. No other danger was observed.

The similarities in intended uses, operational characteristics, and functional technological characteristics between the AIR-N-GO, the EMS AIR-FLOW handy PERIO, the EMS AIR-FLOW handy 2 and the EMS AIR-FLOW MASTER lead to a conclusion of substantial equivalence between the proposed and predicate device. The AIR-N-GO device is substantially equivalent to the selected predicates.

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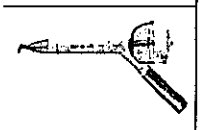
14.b) Technical Specification Comparison

The AIR-N-GO technical specifications are similar to the predicate devices EMS AIR-FLOW handy PERIO, EMS AIR-FLOW handy 2 and EMS AIR-FLOW MASTER which already cleared for dental indications.

A direct comparison of the basic specification and performances of the AIR-N-GO with the predicate devices is summarized in Table 2.

TABLE 2- Technical Specifications and Performance Comparison

	New Device	Predicate 1	Predicate 2	Predicate 3	*Impact of the differences*
Device name	AIR-N-GO	EMS AIR-FLOW handy PERIO	EMS AIR-FLOW handy 2	EMS AIR-FLOW MASTER	
Weight	0.160 kg	0.160 kg	0.160 kg	5 Kg	
Pictures					
Operation mode	Continuous	Continuous	Continuous	Continuous	*No difference*
Input Water supply pressure	3 Bars max	0,7 à 1,5 bar	0,7 à 2,2 bar	1 à 5 Bars	*No impact*
Input Water flow	10 to 20 ml/min	20 to 80 ml/min	50 to 80 ml/min	Not communicated	*10 to 20 ml/min are current value for use.*
Input Air Supply pressure	3 to 4 Bars	3 to 4 Bars	3,5 to 4,5 Bars	5.5 à 7.5 Bars	*No impact*
Operating conditions	+10°C to +40°C	+10°C to +40°C	+10°C to +40°C	+10°C to +40°C	*No impact*
Storage and transport conditions	- 20°C to + 70°C	-10 °C to +40 °C	-10°C to +40°C	-10°C to +40°C	*No impact*

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14. c) Technology, Features, Materials and nozzle, Comparison

A direct comparison of the basic system technology, features, materials and nozzles of the AIR-N-GO with the predicate devices is summarized in Table 3.

TABLE 3 - Technology, Features, Materials Comparison

	New Device	Predicate 1	Predicate 2	Predicate 3	*Impact of the differences*
Device name	AIR-N-GO	EMS AIR-FLOW handy PERIO	EMS AIR-FLOW handy2	EMS AIR-FLOW MASTER	
Supply	Air and Water	Air and Water	Air And Water	Air, Water, and Electric Power	*There is no electrical power supply*
Type	Handpiece	Handpiece	Handpiece	Handpiece	*No difference*
Technology	Connected on dental operative units	Connected on dental operative units	Connected on dental operative units	Connected to the mains. Table top unit	*More convenient to use*
Handpiece Material	Plastic and metal	Plastic and metal	Plastic and metal	Plastic and metal	*No difference*
Stop Powder	Yes	No	No	No	*Allows rinsing the clinical site and the device*
Head	Long head Short Head	Yes	Yes	PERIO handpiece and SUPRA handpiece	*More convenient to use*
SUPRA Nozzle	Nozzle 90° Nozzle 120° (Reusable)	NO	Nozzle 90° Nozzle 120° (Reusable)	Nozzle fixed on the handpiece (Reusable)	*No difference*
PERIO Nozzle	Yes (reusable)	Yes (single use)	No	Yes (single use)	*Economical aspect. Less money spending*
Cleaning Probe	Yes	Yes	Yes	Yes	*No difference*
Tank	PERIO Tank or SUPRA tank on the rear of the device	On the middle of the device	On the middle of the device	PERIO Tank and SUPRA tank on the table top unit	*Better visibility and usability*
Supra-gingival use	Yes	No	Yes	Yes	*No difference*
Sub-gingival use	Yes	Yes	No	Yes	*No difference*

15. Determination of Substantial Equivalence

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Does New Device Have Same Indication Statements?

The AIR-N-GO indications for use are similar to the EMS AIR-FLOW handy PERIO for sub-gingival dental applications (PERIO). The AIR-N-GO indications for use are similar to the EMS AIR-FLOW handy 2 for supra-gingival dental applications (SUPRA). The AIR-N-GO indications for use are similar to the EMS AIR-FLOW MASTER for (PERIO) sub-gingival dental applications (PERIO) and supra-gingival dental applications (SUPRA).

Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?

The AIR-N-GO is the same as the EMS AIR-FLOW handy PERIO (K092289) predicate device in terms of principle. Both systems consist of a dental handpiece intended for the projection of a mixture of air, water and dental powder on the surface of teeth in sub-gingival dental applications. Also, both systems are composed of a tank, and lid tank and PERIO Nozzle. Both systems are connected to dental operative units with a turbine connector.

The AIR-N-GO is the same principle as the EMS AIR-FLOW handy 2 (K022119) predicate device in terms of principle. Both systems consist of a dental handpiece intended for the projection of a mixture of air, water and dental powder on the surface of teeth in supra-gingival dental application. Also, both systems are composed of a tank, and lid tank and 90° and 120° SUPRA Nozzle. Both systems are connected to dental operative units with a turbine connector.

The AIR-N-GO is the same principle as the EMS AIR-FLOW MASTER (K082791) predicate device in terms of principle. Both systems consist of a dental handpiece intended for the projection of a mixture of air, water and dental powder on the surface of teeth in supra-gingival dental application and sub-gingival dental applications. Both systems can be used for supra-gingival dental application and sub-gingival dental applications.

Is there a Summary of the non-clinical testing?

The evaluation was to demonstrate the substantial equivalence of the AIR-N-GO device and these selected predicates. In order to facilitate the evaluation, the devices were categorized in two groups according to their clinical applications: SUPRA for supra-gingival application and SUB for Sub-gingival application.

For the supra-gingival applications, the AIR-N-GO and the predicates have been tested on the upper jaw central incisor of a dental study model. A coat of varnish has been applied repeatedly on the same tooth or implant and each device has been used to remove it. The results obtained are quite similar between each system. The varnish was completely eliminated and the tooth surface treated remained intact. In terms of time efficiency the main difference remains on the use of the supra handpiece of the tabletop unit. It can be explained by the fact the device receives a pressure which is fairly high compared to the turbine connection systems. No other danger was observed.

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For the sub-gingival application the AIR-N-GO and the predicates have been be tested first on the root of the upper jaw central incisor of a dental study model .Then, the devices have been be tested on an implant replica located on the lower jaw molar. The varnish has been applied up to 5 mm. The devices have been used to remove varnish on root tooth or implant to verify the effectiveness and integrity of surface. The nozzle has been inserted up to 5mm in the pocket. The results obtained are quite similar between each system. There are no significant differences of the efficiency of removal of varnish between tooth and implant.

Could the New Characteristics Affect Safety or Effectiveness?

The AIR-N-GO is not a clinical innovation and the use is very well known by the practitioners. The AIR-N-GO is the same as the identified predicates in terms of clinical application. Also the used technologies and characteristics are similar to the predicates. The characteristics of the AIR-N-GO used with recommended dental powders do not affect the Safety of the patients or of the operator. Moreover, *the AIR-N-GO device it is substantially equivalent to the declared predicate devices.*

Conclusion

Based on the intended use and the technical characteristics of, the AIR-N-GO device it is substantially equivalent to the declared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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SATELEC
C/O Mr. Rick Rosati
Quality Manager
ACTEON, Incorporated
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DEC - 8 2011

Re: K110379
Trade/Device Name: AIR-N-GO
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 15, 2011
Received: September 16, 2011

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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: K110379

Device Name: **AIR-N-GO**

Indications for Use:

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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)

Susan Runner

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

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