MAR 2 1 2005

K043497

510(k) SUMMARY

J. MORITA MFG. CORP.'s
Air Solfy

Name of Device and Name/Address of Sponsor

Trade or Proprietary Name:	Air Solfy AS series (AS-4H/ AS-4H-O/ AS-4H-V/ AS-4H-OV and AS-1/ AS-1-O/ AS-1-V/ AS-1-OV)
Common Name:	Dental scaler
Classification Name:	Dental Handpiece and accessories (21CFR872.4200)
Product Code :	EFB ("Handpiece, Air-powered, Dental)

Registration No. 2081055
Initial Distributor:
J. Morita USA, Inc.
9 Mason
Irvine, CA 92618
USA
Telephone: 949-581-9600
Facsimile: 949-581-9688

Registration No. 3002807636
Manufacturer:
J. MORITA MFG. CORP.
680 Higashihama Minami-cho
Fushimi-ku, Kyoto
Japan 612-8533
+81-75-611-2141
+81-75-605-2354

Intended Use

The Air Solfy can be used to remove calculus deposits from teeth by application of an air-powered vibrating scaler tip from the teeth during dental cleaning and periodontal therapy.

Technological Characteristics and Substantial Equivalence

This device receives energy resorces in handpiece such as air for high speed air turbine, cooling water for scaling and light source for illumination, through the tubes connected to a dental unit.

The cooling water is fed on the part of scaling treatment through pouring holes.

Air Solfy is classified into the model as is shown below Table-1 from the variations of connection, light or power adjuster.

Table-1 Model of Air Solfy

(- : not included)

Model	Connection	Light	Power Adjuster	Autoclave
AS-1	They can be connected to the MORITA original α joint.	-	-	Autoclavable
AS-1-O		Included	-	
AS-1 V		-	Included	
AS-1-O V		Included	Included	
AS-4H	They can be connected to the CP4 or CP4-O coupling. NOTE-1	-	-	Autoclavable
AS-4H-O		Included	-	
AS-4H V		-	Included	
AS-4H-O V		Included	Included	

NOTE-1 CP4 or CP4-O is the ISO9168 type C coupling.

Air Solfy covered by this submission is substantially equivalent to other legally marketed device. Specifically, Air Solfy is substantially equivalent to the Siroair L air scaler from Sirona dental syatem , Inc(K#033812). Air Solfy has similar general intended uses, similar principles of operation, and similar technological characteristics as the previously cleared predicate device, Siroair L air scaler.

Although we cannot compare specifications of them minutely as we have not obtained the details of specifications of Siroair L, but we are able to figure out the specifications and equivalence as there exists a common international standard on the dental air-powered handpiece of ISO 15606. Air Solfy is in compliance with ISO 15606:1999.

The Air Solfy's substantial equivalence to Siroair L is demonstrated at Comparison Summary Table as below.

Although there are minor differences in the characteristics of Air Solfy and its predicate device, these differences do not raise new questions of safety or effectiveness.

Substantial Equivalent comparison table

FDA file reference number	510k number K033812
Attachment inside notification submission file	510k FDA
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indication for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Similar
Anatomical sites	Similar
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Not applicable
Radiation safety	Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2005

J. Morita USA, Incorporated
C/O Mr. Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W. 11th Floor
Washington, DC 20005

Re: K043497
Trade/Device Name: Air Solfy Air Powered Dental Handpiece Scaler and Tips
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: March 3, 2005
Received: March 4, 2005

Dear Mr. Barritt:

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.

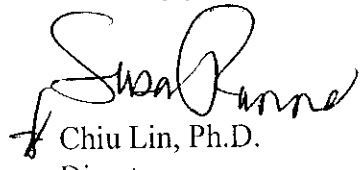
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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 (if known): K043497

Device Name: AIR SOLFY AIR POWERED DENTAL HANDPIECE SCALER AND TIPS

Indications For Use:

The Air Solfy is a dental air-powered handpiece scaler and tips that can remove calculus deposits from the teeth by application of an air-powered vibrating scaler tip to the teeth during dental cleaning and periodontal therapy.

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

(510(k) Number) K043497