K043498

FEB 16 2005

510(k) SUMMARY

J. MORITA MFG. CORP.'s
TWIN POWER TURBINE 4H/DI

1. Submitter Name and Address with Phone/Fax :

Registration No. 2081055	Registration No. 3002807636
Initial Distributor:	Manufacturer:
J. Morita USA, Inc.	J. MORITA MFG. CORP.
9 Mason	680 Higashihama Minami-cho
Irvine, CA 92618	Fushimi-ku, Kyoto
USA	Japan 612-8533
Telephone: 949-581-9600	+81-75-611-2141
Facsimile: 949-581-9688	+81-75-605-2354

2. Contact Person

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

3. Date summary prepared: September 29, 2004

4. Device Name:

Trade or Proprietary Name: TWIN POWER TURBINE PAR series
PAR-4H series
(PAR-4HE/ PAR-4HE-O/ PAR-4HS/ PAR-4HS-O)
PAR-DI series
(PAR-E-DI/ PARE-O-DI/ PAR-S-DI/ PAR-S-O-DI
PAR-M-DI/ PAR-M-O-DI)

Common Name: Air powered dental handpiece

Classification Name: Dental handpiece and accessories
(21CFR 872.4200)

Product Code : EFB ("Handpiece, Air-powered, Dental ")

5. Substantial Equivalency is claimed against the following device:
Synea-HS High-Speed Handpiece from A-Dec, Incorporated (K992011) .

6. Description of the device:

Ⅶ-1 DEVICE DESCRIPTION

TWIN POWER TURBINE is a dental handpiece

This device receives energy resources in handpiece such as air for high speed air turbine, cooling water for cutting and light source for illumination, through the tubes connected to a dental unit.
The cooling water is fed part of cutting treatment through pouring holes.

TWIN POWER TURBINE is classified into the model as is shown below Table-1 from the variations of light and motor.

Table-1 Models of PAR series

(-: not included)

Name	Model	Main Body			Coupling	
		Body	Light	Head assembly	4-hole coupling	Tube connection ISO9168
TWIN POWER TURVINE 4H PAR-4Hseries	PAR-4HE	PAR-4HE	-	Standard	CP-4, CP4-A or CP4-W	Type-B
	PAR-4HE-O	PAR-4HE-O	Included	Standard	CP4-O, CP4-AO or CP4-WO	Type-C
	PAR-4HS	PAR-4HS	-	Torque-up	CP-4, CP4-A or CP4-W	Type-B
	PAR-4HS-O	PAR-4HS-O	Included	Torque-up	CP4-O, CP4-AO or CP4-WO	Type-C
TWIN POWER TURVINE P PAR-DIseries	PAR-E DI	PAR-E DI	-	Standard	-	-
	PAR-E-O DI	PAR-E-O DI	Included	Standard	-	-
	PAR-S DI	PAR-S DI	-	Torque-up	-	-
	PAR-S-O DI	PAR-S-O DI	Included	Torque-up	-	-
	PAR-M DI	PAR-M DI	-	Miniature	-	-
	PAR-M-O DI	PAR-M-O DI	Included	Miniature	-	-

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7. Intended Use

TWIN POWER TUBINE is for use by authorized persons in the practice of the dentistry.

8. Safety and effectiveness of the device

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison as below.

Substantial Equivalent comparison summary table

The predicate device and its 510k number: Synea-HS High-Speed Handpiece from A-Dec, Incorporated K992011 **Attachment inside notification submission file** The promotional materials of its predicate device, Attachment 3	
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

FEB 16 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: K043498
Trade/Device Name: Twin Power Turbine High Speed Air Turbine Dental Handpiece
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: December 16, 2004
Received: December 17, 2004

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- . 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

K043498

Indications for Use

510(k) Number (if known): K#043498

Device Name: TWIN POWER TURBINE high speed air turbine dental handpiece

Indications For Use:

The TWIN POWER TURBINE handpiece is for use by authorized persons in the practice of dentistry.

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)

[signature]

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...(k) Number K043498