DEC 22 2004

SECTION 10

510(k) Summary

Submitter: NOUVAG AG
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Date Summary Prepared: October 08, 2004

Device Name:

Proprietary Name	TCM Endo V
Common Name	Endodontic Device with Apex locator
Classification Name	Handpiece, Direct Drive, Ac-powered (per 21 CFR section 872.4200)

Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

J. Morita USA, Inc.
DENTAPORT ZX
K031204, Cleared on 08/21/2003

J. Morita USA, Inc.
DENTA PORT
K022147, Cleared on 12/20/2002

Device Description:

The TCM Endo V is a transportable, cord connected, microprocessor-controlled endodontic device with Apex Locator. It is provided with a plastic enclosure which has four electrical connection ports for the detachable power supply cord, the foot-control, the micro-motor and the reference electrode (lip connector).
The Apex Locator measures the distance between file tip and Apex. If a minimum distance is preselected, the selected auto-control mode is activated thus ensuring that the minimum distance is reached.
The speed is held constantly under all circumstances until the maximum adjusted torque limit is reached. The Automatic Torque Control (ATC) protection mode ensures that no file breakage occurs. Once the preselected torque limit has been reached, the motor will immediately reverse for one revolution, then returns to forward direction. This ensures a fast and effective root canal preparation.

The following parameters can be set by the user:
- mains voltage (100V/115V/230V)
- rotational speed (150-2000 rpm)
- "Apex adjust" (-1 to 0)
- automatic torque limitation "ATC" (5-40Nmm)
- "Auto control" mode ("Auto Slow / Down", "Auto Reverse"; "Auto Stop")
- micro-motor ON/OFF "Motor"

Sterility:
Contra Angle, Motor and motor cable, and lip connector: Sterility by user up to 134°C.

Intended use of the Devices:

The TCM Endo V is a dental root canal measurement and treatment device that can measure the length of the root canal and enlarge the root canal while monitoring the position of the file tip inside the canal.

Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The TCM Endo V is substantially equivalent to other legally marketed devices in the United States. The TCM Endo V functions in a manner similar and are intended for the same use as the Devices designed by J. Morita USA, Inc.

Brief summary of nonclinical tests and results:

The TCM Endo V has been designed and tested to applicable safety standards. The TCM Endo V does not raise any new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2004

NOUVAG AG
C/O Mr. Erich Forster
Regulatory Consultant
INTRATest Systems GmbH
Reusswehrstrasse 1
CH-5412 Gebenstorf / Switzerland

Re: K042822
Trade/Device Name: TCM Endo V
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Access Series
Regulatory Class: I
Product Code: EKX
Dated: October 8, 2004
Received: October 12, 2004

Dear Mr. Forster:

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/dsma/dsmamain.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

510(k) Number (if known): K042822

Device Name: TCM Endo V

Indications for Use:

The TCM Endo V is a dental root canal measurement and treatment device that can measure the length of the root canal and enlarge the canal while monitoring the position of the file tip inside the canal.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

Prescription use X OR Over-The-Counter Use_____
(per 21 CFR 801.109)

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

510(k) Number: K042822