K081191

SECTION 5

AUG - 7 2008

510(k) Summary

Submitter: NOUVAG AG
St. Gallerstrasse 23-25
CH-9403 Goldach
Switzerland

Contact Person: Markus Gemperle
Quality Manager / RA
Phone +41 71 846 66 00
Fax +41 71 845 35 36

Date Summary Prepared: April 16, 2008

Device Name:

Proprietary Name	TCM Endo 20
Common Name	Endodontic Device
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:

NOUVAG AG
TCM Endo V
K042822, Cleared on 12/22/2004

Device Description:

The TCM Endo 20 is a transportable, cord connected equipment, provided with a plastic enclosure which has two connection ports for the footswitch and the electronic motor.
It is a microprocessor controlled electronic motor system which controls the rotational speed and the torque of the motor. The rotational speed is constant until the torque reaches the adjusted level.
In order to protect the rimmer, you can choose between two torque controlling modes – the Automatic Limiter (AL) and the Automatic Reverse (AR) mode.
The electronic motor has a standard E-type handpiece adapter that accepts any E-type contra angle and handpiece (E-fitting).

The following parameters can be set by the user:

- "Speed" – increase or decrease rotational speed
- "Torque" – select torque maximum
- "Motor" – Switch on/off electronic motor
- "Ratio" – Select ratio of the contra angle
- "Symbol reverse" – Select rotating direction: R (Right) clockwise; L (Left, reverse) counterclockwise
- "Prog" – Select Program 1 to 9
- "AL/AR" - Choose between AL- and AR- mode

Sterility:
Motor and motor cable: Sterility by user up to 134°C.

Intended use of the Devices:

The TCM Endo 20 is a dental root treatment device for enlarge the root canal with a rotating, high elastic file.

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

The TCM Endo 20 is substantially equivalent to other legally marketed devices in the United States. The TCM Endo 20 functions in a manner similar and is intended for the same use as the TCM Endo V (Predicate device)

Brief summary of nonclinical tests and results:

The TCM Endo 20 has been designed and tested to applicable safety standards.
The TCM Endo 20 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

AUG - 7 2008

NOUVAG AG
C/O Ms. Erich Forster
Quality Manager / Regulatory Affairs
INTRATest GmbH
Reusswehrstrasse 1
Gebenstorf
CH-5412
SWITZERLAND

Re: K081191
Trade/Device Names: TCM Endo 20
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: July 8, 2008
Received: July 14, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

K081191

510(k) Number (if known): _____

Device Name: TCM Endo 20

Indications for Use:

The TCM Endo 20 is a dental root treatment device for enlarge the root canal with a rotating, high elastic file.

(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)

Susan Runner

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

510(k) Number: K081191