NOV 2 8 2001

K013185

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Nouvag, A.G.
St. Gallerstrasse, 23-25
CH-9403 Goldach
Switzerland

Contact:

Colleen Boswell
Sybron Dental Specialties, Inc.
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile

Date Summary Prepared: September 2001

Device Name:

- Trade Name – *TCM Endo III*
- Common Name – AC-Powered Dental handpiece
- Classification Name – Dental Handpiece and Accessories, per 21 CFR § 872.4200

Devices for Which Substantial Equivalence is Claimed:

- Analytic Endodontics, *Quantec-E Endo System*

Device Description:

The *TCM Endo III* is an AC-powdered endodontic unit consisting of a controller console, foot pedal and motor intended to drive dental handpieces during root canal preparation. The motor has a maximum 1:1 drive output of 16,000 Rpm's. The unit is supplied with either a 115V or 230V power cord. The entire motor assembly of the *TCM Endo III* is autoclavable.

Intended Use of the Device:

The intended use of the *TCM Endo III* is to drive dental handpieces during root canal preparation.

Substantial Equivalence:
TCM Endo III is substantially equivalent to other legally marketed devices in the United States. *TCM Endo III* functions in a manner similar to and is intended for the same use as the *Quantec-E Endo System* designed by Analytic Endodontics.

1717 West Collins Avenue, Orange, CA 92867 800-537-7824 714-516-7400

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2001

Nouvag AG
C/O Ms. Colleen Boswell
Consultant
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K013185
Trade/Device Name: TCM Endo III
Regulation Number: 872.4200
Regulation Name: AC-Powered Dental Handpiece
Regulatory Class: I
Product Code: EFA
Dated: September 21, 2001
Received: September 24, 2001

Dear Ms. Boswell:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Nouvag, A.G.

510(k) Number (if known): K013185

Device Name: TCM Endo III

Indications For Use:

The *TCM Endo III* is an AC-powdered endodontic unit consisting of a controller console, foot pedal and motor intended to drive dental handpieces during root canal preparation.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013185

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)