SEP 28 1999

K993188

phytron

510(k) SUMMARY per 21 CFR 807.92(a)(2)

I. Submitter:

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Germany
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II. Date: 510 (k) Summary has been prepared on August 19th, 1999

III. Reason for 510(k) submission:

It is intended to put this device into commercial distribution for the first time.

IV. Trade Name:

EndoStepper® 1

V. Classification Name:

Dental Handpiece and Accessories (21 C.F.R. § 872.4200)

VI. Classification:

The device is a general control of class I according to 21 CFR 872.4200.

VI. Predicate Device:

TCM 3000/Endo
manufacturer:
Nouvag AG
St. Gallerstraße 23-25
CH-9403 Goldbach
Switzerland

VII. Device Description:

The EndoStepper System is an electronically controlled drive for dental drilling applications. The system consists of (1) a console type housing containing the electronics with a LCD display and a keypad, (2) a foot pedal unit, (3) a drive unit to be used with (4) a protective cover and a commercially available contra-angle.

VIII. Intended Use:

The EndoStepper 1 system is a microcontroller controlled dental handpiece based on a stepper motor.

It's intended use is for dental drilling applications and other dental treatments, where a smooth and slowly rotating drive is required, e.g. the for polishing dental surfaces, caries removal and root canal preparation.

The EndoStepper 1 system is to be used by practising dentists only.

IX. Technological Characteristics:

The EndoStepper 1 system consists of a console type desktop housing with the electronics, a motor with a protective cover, a foot pedal and an electric cord and plug. The system can be used with commercially available contra-angles with an internal gear reduction ratio of 1:1.

The EndoStepper uses a stepper motor as the driving element. This special motor type has the advantage, that delivered torque as well as speed and angle of rotation can easily be controlled.

Therefore the EndoStepper delivers a precisely controlled torque together at a precisely controlled speed of rotation, and, in special operation modes, also a well defined maximum angle of rotation can be guaranteed.

Principles of Operation

After switching on the device, self-tests of the system hardware are performed.

After the power-on self test procedure, the system display a menu text on the LCD display. The dentist can now select the dental instrument (e.g. drill) he is going to use by means of the menu driven selection.

The operator selects now the manufacturer, the drill series he wants to use and then the special drill identified by its diameter and color code. These selections are made by means of the keypad or - alternatively - by means of the foot pedal. Every selection can be controlled on the LCD display in plain text.

The drive unit is locked and will not start to operate until the operator selected one special drill type. After the selection, the motor can be started by means of the foot pedal. The motor will then operate the drill with the speed of rotation and the torque limit set as defined by the drill manufacturer itself, as these values are programmed into the device.

The operator has only to select the appropriate parameter record, and this selection is made safe and effective by means of a plain text LCD display. No other parameter settings are necessary, such yielding a safety never seen before while selecting an instrument.

The drive unit is based on a stepper motor. This is a special type of a synchonous motor, which will develop a rotational torque directly dependend on the motor current. Because the motor current is controlled in the electronics, the motor will deliver only torque values up to this well defined limit value.

If this limit is exceeded, e.g. due to friction on the dental instrument in a root canal, the motor stops immediately due to its physical structure. The subtle root canal instrument is therefore effectively protected and not exposed to mechanical overload.

Overview over Substantial Equivalence Comparison

The following table shows the substantial equivalence between the proposed EndoStepper 1 system and the predicate device, the TCM Endo (FDA-No. K981679).

Feature	TCM Endo	EndoStepper®	Substantial Equivalence
Intended use	a, micro-processor controlled dental handpiece with controlled electric motor torque b, dental drilling applications	micro-processor controlled dental hand-piece with controlled electric motor torque b, general dental drilling applications	YES
Input voltage	115 V / 230 V 50/60 Hz	115 V / 230 V 50/60 Hz	YES
Materials	Electronic parts and components	same	YES
Indications for use	Dental drilling applications, especially endodontic drilling	same	YES
Torque control	yes	yes	YES
Torque control precision	1 Ncm	better than 0.1 Ncm	YES / Better
System reaction in case of blocking	Reverse motion with undefined angle of rotation and continuation without dentist intervention	motor stops within several degrees of rotation; dentist can decide by himself how to proceed	YES / Better

X. Overview over Standards Applied During the Development

Device Safety:	IEC 601-1, IEC 601-1-2, IEC-1-4 (as equivalent and fully corresponding to the European standards EN 60601-1, EN 60601-1-2, EN 60601-1-4)
Device Effectiveness:	Appendix I of the European Directive for Medical Devices (MDD)
EMC Compatibility:	IEC 601-1-2 with reference to EN 55011, EN 61000-4-2, EN 61000-4-3, EN 61000-4-4, EN 61000-4-5; conformity has been certified during an independent examination by a competent body.
Drive Parameters:	ISO 3630-1, ISO 3630-2 ISO 3630-3 and manufacturer's specification if not covered by the standard
Coupling Dimensions:	ISO 3964

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 1999

Phytron-Elektronik GmbH
C/O Ms. Carole Stamp
TPR Project manager
TUV Product Service, Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K993188
Trade Name: EndoStepper® 1
Regulatory Class: I
Product Code: EKX
Dated: September 23, 1999
Received: September 23, 1999

Dear Ms. Stamp

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your

premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

K993128

Attachment 1b

510(k) Number (if known):_____

Device Name: EndoStepper 1

Indications For Use:

To be used for dental drilling and other dental drive applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993128

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)