2/9/99

K981679

Attachment 8

510(k) SUMMARY FOR NOUVAG AG'S TCM 3000/Endo

Submittors's Name, Address, Telephone Number and Contact Person

Nouvag AG
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As Regulatory Counsel to Nouvag.

Date Prepared

April 28, 1998

Name of Device

TCM 3000 and TCM Endo

Common or Usual Name

Microprocessor-Controlled Dental Drilling and Torque-controlled System

Classification Name

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

Predicate Devices

NOUVAG's Micro-Dispenser 7000 and 8000 (K954722)

Intended Use

Nouvag AG's („Nouvag") TCM 3000 and TCM Endo is a microprocessor-controlled dental hand piece with controlled electric motor-torque. The TCM 3000 and TCM Endo is intended to be used for dental drilling and tightening of the various types of screws during dental implantation and microsurgery. The TCM 3000 and TCM Endo are the same device with the same components. For marketing reason they just have different names.

Technological Characteristics

The TCM 3000's and TCM Endo's primary components are (1) a console; (2) a motor; (3) a microprocessor; (4) a foot pedal; and (5) an electric cord and plug. The TCM 3000 and TCM Endo is not supplied with dental drills or contra-angles or contra-angles torque wrenches, which are also called dental hand pieces. The Micromotor has a standard E-Type coupling that will fit any E-Type hand pieces and contra-angles.

The console houses the microprocessor and the motor. The buttons for setting the motor speed, contra-angle reduction ratio, motor torque are located on the front panel of the console. The buttons that may be used to start and stop the motor and change the cut-direction of the drill also are located on the front panel. The port connections for the contra-angles and the foot pedal and the main power switch are located on the back of the console.

A lever is located on the foot pedal for starting and stopping the motor. For the second version of the foot pedal the lever also can adjust the motor speed. The TCM 3000/Endo contains an audible alarm that sounds when the drill is turning in the reverse- cut direction.

The TCM 3000/Endo requires an AC current of 115V or 230V. An electrical cord, which is intended to be plugged into a standard electrical outlet, is attached to the back of the console.

Principles of Operation

The operator of the TCM 3000/Endo turns the main power switch to the „on" position to start the device. The operator then sets the motor speed, the contra-angle reductions ratio and the motor torque by pressing buttons at the front panel of the console. The preset motor speed is displayed on the front panel. The built - in torque controller ensures that the drill is working constantly at the pre - selected motor torque and the pre - selected drill speed.

The operator also has the option of setting the AS - Torque - Driver Mode. This function is used for tightening and releasing the screws. As soon as the motor torque is equal to the pre-selected value, the motor will automatically shut-off. By utilizing this torque driver mode, the operator can avoid the risk of under - or over - tightening of screws.

The operator starts the motor with the foot pedal or the „motor" button. There are two different foot pedals available: one with just the start/stop foot switch, the second foot control with the variable speed foot pedal. In this case the operator starts cutting with the drill by depressing the lever on the foot pedal; the drill continues to cut as long as the lever remains depressed. The drill stops immediately when the operator releases the foot lever.

The operator can use the drill in the forward-cut direction or the reverse-cut direction pressing the „FORW/REV" button on the control panel. The green LED indicator light on the „FORW/REV" button will illuminate and an alarm will sound when the drill turns in the reverse-cut direction.

The TCM 3000/Endo microprocessor implements the operator's commands, displays the motor speed, and sounds an alarm if there is an electric overload or the drill is turning in the reverse cut direction. The microprocessor has no external user interface; it simply implements the operator's commands. The pre-selected drill speed and motor torque for each drill and the torque value are retained in memory if the main switch is shut off.

Summary of the Basis for the Finding of Substantial Equivalence

The safety or effectiveness of the TCM 3000/Endo is based on the safety or efficacy of the predicate device.

The TCM 3000/Endo and the Micro-Dispenser 7000/8000 have the same general intended use: microprocessor-controlled dental drilling and torque-controlled system. These devices also have very similar indications: dental implantation and oral or microsurgery. In addition, these devices have the same principles of operation. The operator of the device sets the motor speed, contra-angle reduction ratio, and the torque-levels and operates the drill by pushing buttons on the console or on the foot pedal. The operator of the Micro-Dispenser 7000/8000 has the option of operating the drill(s) and changing the cut directions of the drill(s) by using either the hand control buttons on the front panel or the foot pedal. The operator of the TCM 3000/Endo can also use the hand control panel or the foot pedal, but only for start/stop function of the motor. The TCM 3000/Endo and the Micro-Dispenser 7000/8000's microprocessors implement the operator's commands.

The TCM 3000/Endo and the Micro-Dispenser have very similar technological characteristics. More specifically, these dental drilling systems have the following features: (1) buttons on the console for setting the motor speed, torque levels, contra-angle reduction ratios and starting and stopping the motor; (2) a foot pedal for starting and stopping the motor, (3) motor torques that are preset according to the selected contra-angle reduction, (4) safety-overload protection; and (5) they require AC current. Both are microprocessor controlled. Neither device is supplied with drills or contra-angles. Both devices can be used with any E-type contra-angles. Although there are some minor differences in their technological characteristics, namely their contra-angle reduction-ratios and their pre-selectable torque levels, as well their irrigation pump and their foot control. These differences do not present any new issues of safety or effectiveness. Thus, the TCM 3000/Endo is substantially equivalent to the Micro-Dispenser 7000/8000.

The dental drills and contra-angles are the only components of the TCM 3000/Endo that may come into contact with the patient's body during dental implantation or microsurgery. As noted above, the TCM 3000/Endo is not supplied with the dental drills and E-type contra-angles. Therefore, the bio-compatibility of these products need not to be demonstrated in this submission. Nevertheless, the bio-compatibility of dental drills and contra-angles has been demonstrated by their long history of safe use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

Nouvag AG
C/O Ms. Eschbaumer
INTERTest Systems GmbH
Sudetenstrabe 5
D-87600 Kaufbeuren
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Re: K981679
Trade Name: TCM 3000 and TCM Endo
Regulatory Class: I
Product Code: EFB
Dated: November 20, 1998
Received: November 23, 1998

Dear Ms. Eschbaumer

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

510(k) Number (if known): K981679

Device Name: TCM 3000 / Endo

Indications For Use:

To be used for dental drilling and tightening of the various types of screws during dental implantation and microsurgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981679