



SEP 11 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Hiroji Sekiguchi  
Manager and Official Correspondent  
Nakanishi, Incorporated  
340 Kamihinata, Kanuma-Shi  
Tochigi-Ken,  
JAPAN

Re: K011926

Trade/Device Name: Elect-Mate E  
Regulation Number: 872.4200  
Regulation Name: Electric Control Unit with Micromotor  
Regulatory Class: I  
Product Code: EBW  
Dated: June 18, 2001  
Received: June 20, 2001

Dear Mr. Sekiguchi:

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.

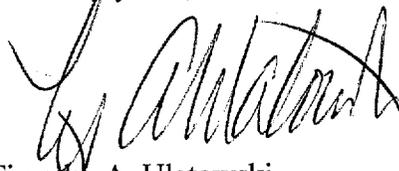
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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 (section 531-542 of the Act; 21); CFR 1000-1050.

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) 594-4613. 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 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

Indications For Use Statement

510(k) Number (if known):                     K011926                    

Device Name:                     Elec-Mate E                    

Indications For Use:

The device is a control unit, which is connected to an ac power supply and a handpiece hose, that drives a dc electric micromotor, and turns on or off or regulates the speed of the motor by the foot control of the dental unit. It has a provision for a low voltage dc power supply for the handpiece with light. It is intended as a control unit for the handpiece used in general dental applications for work such as cutting a tooth for crown preparation, cavity preparation, finishing the crown, inlay or the filling, polishing, prophylaxis and endodontic treatment, with use of straight, right- and contra-angle ISO E-type attachment, with or without internal coolant, of equal, step-up, or step-down speed sheath. The maximum free speed of the electric micromotor is 40,000 rpm.

Special Note:

The electric micromotor and its cord are not autoclavable; therefore, an adequate covering by plastic sleeving as commonly used in dental for infection control method should be used during treatment.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use                        
(Per 21 CFR 801.109)

Over-The-Counter Use                      

                    OR                      
                    Sensen Bunker                      
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number                     K011926                    

(Optional Format 1-2-96)