



APR - 8 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Hiroji Sekiguchi
Marketing Director
Nakanishi, Incorporated
700 Shimohinata
Kanuma-Shi, Tochigi-Ken,
JAPAN

Re: K020327

Trade/Device Name: Surgic IV Dental Implant Unit
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: January 29, 2002
Received: January 31, 2002

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.

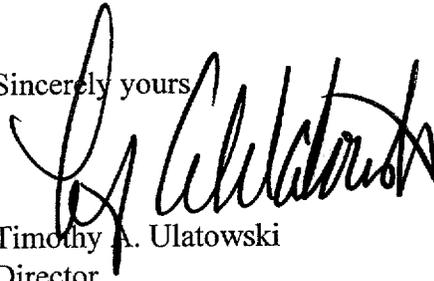
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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 (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

K020327

Indications For Use Statement

510(k) Number (if known): _____

Device Name: Surgic IV Dental Implant Unit

Indications For Use:

The device is a control unit intended to drive contra angles and other attachments that are used with appropriate burs and drills for drilling, reaming, decorticating, and smoothing of bone and other bone related tissue in a variety of dental, oral surgical and other small surgical procedures.

Remarks:

The control unit is equipped with a roller pump to deliver saline solution or sterile water as irrigant to the handpiece. The electric micromotor and its cord are autoclavable. The irrigation tube set use between the irrigation nozzle at the handpiece and the saline solution bottle via roller pump is supplied as an accessory item in the control unit package. It is ETO sterilized for 10⁻⁶ sterility, pyrogen-free.

The control unit has risk of explosion if used in the presence of flammable anesthetics.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Purne

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

510(k) Number K020327

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)