DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 1997

Mr. Hiroji Sekiguchi
International Division II Manager
Official Correspondent
NAKANISHI Incorporated
340 Kamihinata, Kanuma-Shi
Tochigi-Ken
Japan

Re: K972924
Trade Name: Surgic II Implant Control Unit
Regulatory Class: I
Product Code: EBW
Dated: August 7, 1997
Received: August 8, 1997

Dear Mr. Seliguchi:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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):_____

Device Name: Surgic II 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 not autoclavable; therefore, adequate covering by plastic sleeving as commonly used in dental for infection control method is necessary. The irrigation tube set used 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)

Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972924

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

(Optional Format 1-2-96)