

K961381

SEP - 9 1997

EMERGING TECHNOLOGIES GROUP
824 U.S. Highway 1, Suite 370
North Palm Beach, FL 33408

September 17, 1996

RE: 510 (k) Summary- K 96-1381

To Whom It May Concern:

Pursuant to your request, information regarding the above reference **PMN-510 (k)** summary for substantial equivalence of the above referenced document is enclosed. The above referenced devices have been reviewed by CDRH, as well as the Office of Compliance, and have received a substantial equivalence letter.

CREDITED DEVICES

- Dental Imaging Associates- K902433, also Dental Imaging Associates-K902434, Dental Imaging Associates-K902435, and Implant Innovations Inc. preangled abutments-K932123
- Predicate devices for wide body implants, Nobelpharma K925766, Implant Innovations K933462

DEVICE DESCRIPTION

- Endosseous implant system consists of implants, tools and prosthetic abutments. This submission includes premachine angulated abutments less than 30°, specifically included are 15 and 25° abutments. In addition, in the wide body series there are a series of one and two piece prosthetic abutments with 4, 5, and 6mm platform diameters. These diameters match with the platform diameters of the appropriate implant bodies included in this system. This system includes cylindrical and screw implants of a variety of lengths and geometrical shapes. These devices are similar in their intended use and follow the appropriate integration protocol phase and following prosthetic attachments.

INTENDED USE

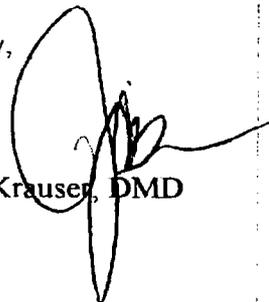
- The implants and wide body implants, as well as abutments and prosthetic system are similar to those of other implant systems in their intended use, which is to facilitate the prosthetic phase and insulation of a prosthesis for the patient.

TECHNOLOGICAL CHARACTERISTIC SUMMARY

- Design, materials, manufacturing processes, gamma sterilization, geometry and materials are similar to the predicate devices currently on the market.
- This PMN includes devices for prosthetic attachment, as well as angled correction, as well as standard and wide body diameters for prosthetic reconstruction phase of the patient case. The materials are ASTM standard, B-348-93 titanium Grade 3, 4, and 5, as well as titanium alloy ELI-Grade 5. GMP guidelines are in place to track the product development and manufacturing processes. The Food and Drug Administration, Office of Compliance has inspected and deemed all stages of the GMP process are in compliance with GMP standards.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,



Jack T. Krauser, DMD

JTK/lb



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 1997

Jack T. Krauser, D.M.D.
The Emerging Technologies Group
824 US Highway 1, Suite 370
N. Palm Beach, Florida 33408

Re: K961381
Trade Name: KIS-III Non-Submerged Implant, Screws and
Cylinders
Regulatory Class: III
Product Code: DZE
Dated: June 9, 1997
Received: June 11, 1997

Dear Dr. Krauser:

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.

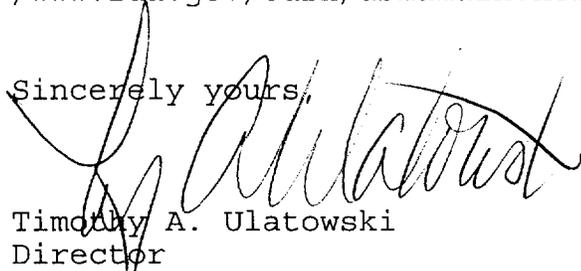
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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

EMERGING TECHNOLOGIES GROUP
824 U.S. Highway 1, Suite 370
North Palm Beach, FL 33408
(516)627-5560

Indication for Use Statement

The NSS-nonsubmerged implant system. These implants and prosthetic implant systems are to be used for the reconstruction of partial and totally edentulous implant patients. The implants are to be used in single or multiple units in the edentulous regions of the maxilla and mandible. The indications range from single tooth application, implant supported partial denture, implant supported bar/overdenture, implant retained overdenture, fixed-detachable implant prosthesis, and totally edentulous implant retained prosthetic designs. The diameter changes of the implant system are to correspond with the maximum available bone width in the treatment areas. Large diameter implants can be utilized to engage the greatest amount of bone volume. These implants can also be used in a submerged protocol if the tissue is thick and a short healing cover screw is utilized. The nonsubmerged protocol does not imply immediate loading, and the implants should integrate in a 3-8 month healing phase based on the bone density before prosthetic load is incorporated into the implant sites.



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K91381