DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 1997

Biomedical Implant Technology, Incorporated
C/O Mr. Ronald McCarley
10304 Islander Drive
Boca Raton, Florida 33498

Re: K962753
Trade Name: Kwan Hexagonal Abutment Implant System (HAIS)
Regulatory Class: III
Product Code: DZE
Dated: October 11, 1996
Received: October 17, 1996

Dear Mr. McCarley:

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 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-320) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

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

REVISED INDICATIONS FOR USE STATEMENT
(revised 1/10/96)

510(k) Number: K962753

Device Name: Kwan hexagonal Abutment Implant System (HAIS)

Indications for Use:

The Kwan HAIS is intended for single tooth replacement, as an intermediate abutment on long span bridgework, as distal abutments on free-end edentulous areas to be restored with fixed bridgework, to support over dentures in totally or partially edentulous arches, and as abutments supporting a full arch fixed prosthesis in the totally edentulous mandible or maxilla. The HAIS is intended to be used in single stage and two stage procedures.

Per 21 CFR 801.109

Note: Underlined portion represents amendment.

MSR

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ion of Dental, Infection Control,
General Hospital Devices

) Number

Prescription Use X
(Per 21 CFR 801.109)