JAN 16 1998

Implant Integration Systems, Inc.

6161 Clark Road, Suite 8 • Paradise, CA 95969 USA • (916) 872-1020 • Fax: (916) 877-7555

K970572

Summary of Safety and Effectiveness Information

The "Dual Integrator" Parallel Pin, Depth Gage, and Surgical Ratchet are all intended to be used with the Implant Integration Systems "Dual Integrator" Dental Implant (K944225).

This product is similar in design, composition (stainless steel) and function to the Minimatic Implant Tech. BC 1208 (K904707), the Impla-Med, Inc. Stainless Steel Instruments (K902911), the Minimatic Implant Tech. DG-1109 Depth Gage (K903115), the Implant Innovations Int. Innovative Implants and Cover Screws (K874590), as well as, parallel pins, depth gauges and surgical ratchets from any other implant system.

Cory D. Hanosh, Sales Manager

2-11-97

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Corey D. Hanosh
Sales Manager
Implant Integration System, Incorporated
6161 Clark Road, Suite 8
Paradise, California 95969

JAN 16 1998

Re: K970572
Trade Name: "Dual Integrator" Dental Implant Accessories
Parallel Pin
Regulatory Class: III
Product Code: DZE
Dated: February 11, 1997
Received: February 14, 1997

Dear Mr. Hanosh:

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

Implant Integration Systems, Inc.

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Indications For Use

This product is designed for use in the placement of the "Dual Integrator" Dental Implant (K944225).

The Parallel Pin is used to insure correct vertical placement of the implant. The Depth Gauge is used to measure the depth of surgical site, while the Surgical Ratchet is used to screw the "Dual Integrator" Dental Implant into the surgical site.

These products along with the "Dual Integrator" Dental Implant make up the total system of tooth replacement by Implant Integration Systems.

Sincerely,

Cory D. Hanosh
Sales Manager

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970572

Prescription Use ✓
(Per 21 CFR 801.109)