510(K) SUMMARY
DIO Implant Systems

14-1. Submitter
DIO Department, DSI, Inc.
117 Kyo-Dong, Yangsan-City
Kyungnam-Do, 626-210, South Korea
Phone: 82-55-363-3401
Fax: 82-55-363-3404

14-2. US Agent / Contact Person
Dr. Steve Chang
13340 E. Firestone Blvd. Suite J
Santa Fe Springs, CA 90670
Phone: 562-404-8466, Fax: 562-404-2757

14-3. Date Prepared
February 05, 2007

14-4. Device Name
DIO IMPLANT SYSTEMS

14-5. Classification Name
Endosseous Dental Implant System

14-6. Device Classification
Class II
Dental Devices panel
21 CFR § 872.3640
Regulation Number: SM® IMPLANT SYSTEMS

14-7. Predicate Devices
SM® IMPLANT SYSTEMS

14-8. Performance
Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

14-9. Device Description

The DIO Implant system includes one-stage fixture and two-stage fixture made of titanium. These implants are surgically inserted into the upper and/or lower jawbone, and serve as a substitute or replacement tooth root providing a stable foundation for restorations.
14-10. Packing / Labeling / Product Information

In a clean room that is Class 10,000 or less, put the product into a capsule, and then put the capsule in a pet container, which is 45mm by 75mm, then sealed the pet container with PERFECSEAL CR27 1073B Coated Tyvek®. DIO Implant Systems (DIO Implant Fixtures, DIO Protective Cap, and DIO Implant System Surgery Tray) will be packaged.

14-11. Indication for Use

The DIO Dental Implant system is an endosseous dental implant that is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units’ prosthetic appliance attachment to restore a patient’s chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on four splinted interforminal placed implants, and not indicated for single, unsplinted implants.

14-12. Substantial Equivalence Comparison

TECHNOLOGICAL CHARACTERISTIC COMPARISON

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIO DENTAL IMPLANT CO. LTD (DIO Implant System)</td>
<td>DIO DENTAL IMPLANT CO. LTD (K061797) (SM® Implant System)</td>
<td></td>
</tr>
<tr>
<td>Intended Use</td>
<td>Identical to predicate devices</td>
<td>DIO Dental implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, terminal or intermediate abutment for fixed bridgework, partial dentures, or single tooth replacements.</td>
</tr>
<tr>
<td>Material</td>
<td>Commercially pure titanium GR. 3 and GR.4 (ASTM-F-67)</td>
<td>Commercially pure titanium GR. 3 and GR.4 (ASTM-F-67)</td>
</tr>
<tr>
<td>Design</td>
<td>Morse Taper with Tread</td>
<td>Morse Taper with Tread</td>
</tr>
<tr>
<td>Screw Threads</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Implant Thread Diameter (mm)</td>
<td>3.5, 4.0, and 4.8 mm</td>
<td>3.8, 4.5, and 5.3 mm</td>
</tr>
<tr>
<td>Collar Height (mm)</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>Lengths (External)</td>
<td>8-14 mm</td>
<td>8-14 mm</td>
</tr>
<tr>
<td>Surface Treatment</td>
<td>Machined</td>
<td>Machined</td>
</tr>
<tr>
<td>Gamma sterilized</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>------------------</td>
<td>---</td>
<td>-----</td>
</tr>
<tr>
<td></td>
<td></td>
<td>YES</td>
</tr>
</tbody>
</table>

**Attachments**

<table>
<thead>
<tr>
<th>Screw-retained restoration system</th>
<th>YES</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cemented restoration system</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Overdenture restoration</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Instruments (surgical and restorative)</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>
Dear Dr. Chang:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indication for Use

510(K) Number (if known): K070570

Device Name: DIO Dental Implant System

Indications For Use:

The DIO Dental Implant system is an endosseous dental implant that is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic appliance attachment to restore a patient’s chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on four splinted interforminal placed implants, and not indicated for single, unsplinted implants.

(Signed)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070570

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)