K983786

NOV 13 1998

SECTION 12.0
510(k) Summary

Company Name:	Sterngold ImplaMed
Address:	23 Frank Mossberg Drive Attleboro, MA 02703
Registration #:	2921595
Contact Person:	Chad Patterson
Date Prepared:	Friday, October 23, 1998

Classification Name:	Endosseous Implant (DZE)
Common Name:	Wide Platform Screw Implant, Wide Diameter, Implant Fixture
Trade Name:	Sterngold ImplaMed Hex Screw Implant, Wide Platform Screw Implant

Device Description
Device consists of titanium screws, and titanium alloy prosthetics, brass and stainless steel restorative components, and stainless steel and titanium alloy surgical instruments.

Intended Use
Device can be used in dental implant applications for oral rehabilitation of endentulous and partially dentate patients in the maxillae and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures.

Technological Characteristics
The modified devices utilize wide diameter titanium screws and related prosthetics and instrumentation. Materials are identical to those currently used in our predicate devices. The wide platform screw products are compatible with current Sterngold ImplaMed installation instrumentation and prosthetic procedures.

Comparative Products
Sterngold ImplaMed currently has permission to market Titanium Screw Implants, Titanium and Titanium alloy prosthetics, and stainless steel instrumentation. Wide platform and diameter screw implants are currently marketed by several companies. Sterngold ImplaMed Wide Platform implants prosthetics and instruments are substantially equivalent to these marketed devices in design, materials, performance and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1998

Mr. Chad Patterson
Director of Product Development
Sterngold ImplaMed
23 Frank Mossberg Drive
Attleboro, Massachusetts 02703-0967

Re: K983786
Trade Name: Sterngold ImplaMed Wide Platform Dental Implants and Related Prosthetics and Instrumentation
Regulatory Class: III
Product Code: DZE
Dated: October 23, 1998
Received: October 27, 1998

Dear Mr. Patterson:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

SECTION 10.0
Indications for Use

Indications:

The Sterngold ImplaMed Implant can be used in dental implant applications for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures.

Prescription Use ✓
(Per 21 CFR 801.109)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983784