AUG 27 2002 K011879

12.0 SUMMARY OF SAFETY AND EFFECTIVENESS

Distributor:	Osseco Biosource, Ltd. 64 Old Orchard, Suite 320 Skokie, Illinois 60077
Regulatory Contact:	Michele H. Vovolka Vantage Consulting International, Ltd
Telephone Number: Fax Number:	847-856-0355 847-856-0357
Date Summary Prepared:	May 29, 2001
Product Trade Name:	3A Dental Implant System
Common Name:	Endosseous Implant
Classification:	Endosseous Implant Class III per 21 CFR 872.3640
Predicate Devices:	Brånemark Nobel Biocare ITI Dental Implant System

Description:

The 3A Dental Implant System is a CP titanium implant that are self-tapping or standard screw-type design. The implant body has a surface finish for either smooth (bright) or textured (abrasive blasted). The implants are available in various insertion lengths and diameters

Intended Uses/Indications:

The ***3A Dental Implant System*** is intended for single or multiple surgical implantation (with or without tissue integration) in the maxillary and or mandibular arches for the purpose of providing prosthetic support for dental restorations in partially or totally edentulous individuals. May be used for single tooth restoration.

Substantial Equivalence:

COMPARISON TABLE

Characteristic	3A Dental Implant Systems	Brånemark Nobel Biocare K993595	ITI Dental Implant System K002374
Indications for Use	Mandible and Maxilla	Same	Same
Design:	External Hex and Morse Taper	Same	Same
Material	Titanium and Titanium Alloy	Same	Same
Implant Sterile	Yes	Same	Same
Implant Diameters	3.75 – 5.5 mm	Equivalent	Equivalent
Implant Lengths	7 – 18 mm	Equivalent	Equivalent
Attachments	Various abutments and components	Equivalent	Equivalent
Product Code	DZE	Same	Same

Summary of Testing:

Testing of a "typical" or representative, standard system configuration utilizing an "angled abutment" was conducted on samples of made of titanium. The testing demonstrated performance sufficient to assure both safe and efficacious use of the implant system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2002

Osseco Biosource, Limited
C/O Ms. Michele H. Vovolka
Vantage Consulting International, Litimed
P.O. Box 848
Grayslake, Illinois 60030

Re: K011879
Trade/Device Name: 3A Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: May 27, 2002
Received: May 29, 2002

Dear Ms. Vovolka:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011879

Device Name: 3A Dental Implant System

Indications For Use:

The ***3A Dental Implant System*** is intended for single or multiple surgical implantation (with or without tissue integration) in the maxillary and or mandibular arches for the purpose of providing prosthetic support for dental restorations in partially or totally edentulous individuals. May be used for single tooth restoration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** _____ **Over -The-Counter Use**
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

510(k) Number K011879