K070184

SECTION 2. SUMMARY AND CERTIFICATION

MAR 24 2008

A. 510(k) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Ospol AB summary for the ***Ospol Dental Implant System*** .

SUBMITTER'S NAME: Ospol AB

ADDRESS: Jorgen Kocksgatan 9, SE211 20 Malmo

CONTACT PERSON: Lennart Carlson

TELEPHONE NUMBER: +46 40 630 76 10

FAX NUMBER: +46 40 23 67 30

DATE OF SUBMISSION: January 10, 2007

1. **Identification of device**
   Proprietary Name: Endosseous Implant and Abutment
   Common Name: ***Ospol Dental Implant System***
   Classification Status: Class II per regulations 872.3640 (implant) and 872.3630 (abutment)
   Product Codes: DZE (implant) and NHA (abutment)

2. **Equivalent devices**
   Ospol AB believes the ***Ospol Dental Implant System*** is substantially equivalent to
   K050705 Nobel Biocare, TiUnite Endosseous Implants
   K053384 Astra Tech, Fixture Micro Thread™ Osseo Speed™

3. **Description of the Device**
   The ***Ospol Dental Implant System*** consists of 4 implants, diameter 4,0 mm, and length from 8,0 to 15,0 mm, 2 standard Abutments (high and low) and 2 Anatomic Abutments (high and low) including healing abutments, cover and abutment screws.

4. **Intended use**
   The Ospol AB, ***Ospol Dental Implant System*** is intended for surgical placement into the bone of upper /lower jaw arches as a permanent anchorage for prosthetic devices and to restore chewing function.

5. **Technological characteristics, comparison to predicate device.**
   Like the predicate devices, the ***Ospol Dental Implant System*** is intended to restore masticator function.

Comparison table

Characteristic	Ospol Dental Implant System	Nobel Biocare TiUnite Implants	Astra Tech Fixture Micro Thread OsseoSpeed	Subst. equivalent
Indication for use	Surgical placement into upper/lower jaw arches as permanent support for prosthetic attachment, to restore masticatory function.	Surgical placement into upper/lower jaw arches as permanent support for prosthetic devices in order to restore patient esthetics and chewing function	Replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla where immediate implant stability may be obtained.	Yes
Dimensions	Diam 4,0 length 8 – 15 mm	Diam 3,3 – 6,0 mm Length 6 – 18 mm	Diam. 4.0 length 8 – 19 mm	Yes
Material	Commercially pure Titanium	Titanium	Titanium	Yes
510(k)	**No number yet**	**K050705**	**K053384**	

6. Discussion of performance testing.

Mechanical testing requested for Screw-type Endosseous Implants are described in the Guideline "Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, dated May 12, 2004.

Ospol AB, ***Ospol Dental Implant System*** is substantially equivalent to Nobel Biocare TiUnite and the Astra Tech Fixture Micro Thread™ Osseo Speed™ in material, dimensions, and indication for use why we have come to the conclusion that further testing will not raise new issues of safety and efficacy.

7. Conclusion

Based on comparison to the predicate device, the Ospol AB, ***Ospol Dental Implant System*** is substantially equivalent to previously cleared predicate systems and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Lennart Carlsson
R&D Manager
Ospol AB
Jorgen Kocksgatan 9
SE-211 20 Malmo
SWEDEN

MAR 24 2008

Re: K070184
Trade/Device Name: Ospol AB, Ospol Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 7, 2008
Received: March 10, 2008

Dear Mr. Carlsson:

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.

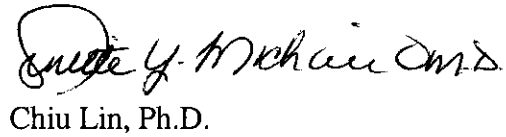
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

B. INDICATIONS FOR USE

510(k) Number K070184

Device Name: Ospol AB, ***Ospol Dental Implant System*** .

Indications for Use:

The Ospol AB, ***Ospol Dental Implant System*** is intended for surgical placement into the bone of upper /lower jaw arches as a permanent anchorage for prosthetic devices and to restore chewing function.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

RSBatz DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070184