K970073

Section 6
510(k) Summary

JUL - 3 1997

letterhead

510(k) Summary

Manufacturer Information:

Submitter's Name:	Steri-Oss Inc.
Address:	22895 Eastpark Drive Yorba Linda, CA 92887, U.S.A.
Contact's Name:	Jeff Hausheer, Ph.D. Regulatory Affairs Specialist
Phone:	714-282-4800, extension 3815
Date Prepared:	January 1997

Device Names:

Common Name: Endosseous Dental Implant Abutment and Lingual Retaining Screw

Trade Name: Bio-Esthetic Indirect Abutment

Classification Name: Endosseous implant

Predicate Device:

Substantial equivalence is claimed to Friatec's "Frialit-2 MH-6 Abutment".

Device Description:

How device functions: The Steri-Oss Lingual Bio-Esthetic Indirect Abutment is designed to be used in conjunction with endosseous implants as part of a system to provide support for prosthetic appliances to restore patient chewing function, and includes utilization of a lingual retaining screw for abutment retention which allows retrievability.

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510(k) Summary (continued)

Device Description (continued):

Scientific concepts: Natural dentition is composed of a root (subgingival) and a crown (supragingival). Implant system designs in existence are intended to mimic this structure to aid the patient in restoring natural masticatory function. The implant is designed to serve as the root of the artificial tooth and the abutment/prosthetic is designed to serve as the crown. The abutment must be securely fastened to the implant. A lingual retaining screw may be used for this purpose, while retaining retrievability.

Characteristics: The Bio-Esthetic Indirect Abutment is a conventional abutment designed for use with a lingual screw which, when tightened, retains the abutment in place.

Intended Use:

The intended use of Steri-Oss' Bio-Esthetic Indirect Abutment, an abutment retained with a lingual retaining screw, is to provide a stable, secure foundation upon which a prosthetic appliance (the purpose of which is restoration of masticatory function in the edentulous or partially edentulous patient) can be attached, yet remain retrievable.

Comparison to Predicate:

Table 6.1 provides a comparison of the technological characteristic of the Steri-Oss implant to the predicate.

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Table 6.1

Product Comparison - Abutment with Lingual Retaining Screw

Characteristic	PREDICATE Friatec's "Frialit MH-6 Abutment"	NEW DEVICE Steri-Oss' Bio-Esthetic Indirect Abutment
Abutment and Screw Material	Titanium alloy	Same
Retaining Screw Cpllar Material	Gold alloy	Gold alloy
Abutment Design	Cylindrical shape	Oval cylinder shape with and without angulation
Height (mm)	0.130 in. to 0.256 in.	0.350 in. to 0.0359 in.
Maximum Diameter (mm)	0.067 in. to 0.110 in.	0.230 in. to 0.283 in.
Abutment Angulation	Straight	Straight and 15°
Packaging	Unknown	Chevron pouch in plastic case
Sterility	Unknown	Provided Sterile

Performance Data:

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 17 2010

Ms. Phuong Nguyen Son
Regulatory Affairs Manager
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K970073
Trade/Device Name: Bio-Esthetic Indirect Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Bio-Esthetic Indirect Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 28, 2010
Received: July 29, 2010

Dear Ms. Nguyen Son:

This letter corrects our substantially equivalent letter of July 28, 2010.

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 (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.

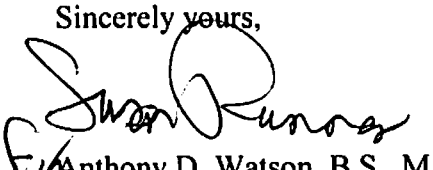
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control
Office of Device Evaluation
Center for Devices and
Radiological Health

Original 510(k)
Bio-Esthetic Indirect Abutment

Section 9

Indications for Use

510(k) Number (if known): K970073

Device Name: Bio-Esthetic Indirect Abutment

Indications For Use:

The intended use of Steri-Oss' Bio-Esthetic Indirect Abutment, an abutment retained with a lingual retaining screw, is to provide a stable, secure foundation upon which a prosthetic appliance (the purpose of which is restoration of masticatory function in the edentulous and partially edentulous patient) can be attached, yet remain retrievable.

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

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K970073

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)