NOV 23 1999

K992538

Section 6
510(k) Summary

Manufacturer Information:

Submitter's Name:	Nobel Biocare USA, Inc.
Address:	22895 Eastpark Drive Yorba Linda, CA 92887 USA
Contact Name:	Kim Rendon Regulatory Affairs Analyst
Phone:	714-282-4800
Date Prepared:	July 1999

Device Name:

Common Name:	Prosthetic Attachment Screw.
Trade Name:	Amorphous Diamond Coated Screw.
Classification Name:	Endosseous Dental Implant.

Predicate Device:

Substantial equivalence is claimed to the Nobel Biocare USA, Inc. Steri-Oss Tiodized Screw, 510(k) K964739, approved February 27, 1997.

Device Description:

Device Function: The Amorphous Diamond Coated Screw is designed to fasten prosthetic components to implants and/or other prosthetic components. The attachment is secured by applying torque to the screw.

Scientific Concepts: Screws used to fasten prosthetic components can some times loosen. The greater the preload that is applied, the less chance there is that the screw will eventually become loose. Titanium screws with an amorphous diamond coating applied to the working length of the screw

underneath the head, can be preloaded to a much greater torque than uncoated screws and thus are less likely to loosen.

Characteristics: The Amorphous Diamond Coated Screw is constructed of titanium alloy with an amorphous diamond coating applied to the working length of the screw underneath the head.

Intended Use:

The Amorphous Diamond Coated Screw is used to retain prosthetic components to dental implants or to other prosthetic components. The amorphous diamond coating will add a greater preload to the screw, which in turn help prevent the screw and prosthetic components from loosening.

Comparison to Predicate:

Characteristic	**Steri-Oss Tiodized Screw**	**Amorphous Diamond Coated Screw**
Material	Titanium Alloy	Same
Surfactant	Anodized Titanium Alloy	Amorphous Diamond Coating
Geometry	Threaded Screw	Same
Screw Design (for driver)	Internally Hexed	Same
Intended Use	Fasten Steri-Oss System Prosthetic Components	Same
Packaging	Chevron pouch in plastic case	Same
Sterility	Sterile	Same

Performance Data:

Biological and mechanical test data were performed to support the indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 1999

Ms. Kim Rendon
Regulatory Affairs Analyst
Nobel Biocare USA, Inc.
22895 Eastpark Drive
Yorba Linda, CA 92887

Re: K992538
Trade Name: Amorphous Diamond Coated Screw
Regulatory Class: III
Product Code: DZE
Dated: July 28, 1999
Received: July 30, 1999

Dear Ms. Rendon:

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 8
Indications for Use

510(k) Number (if known): K992538

Device Name: Amorphous Diamond Coated Screw

Indications For Use:

The Amorphous Diamond Coated Screw is used to retain prosthetic components to dental implants or to other prosthetic components. The amorphous diamond coating will add a greater pre-load to the screw, which in turn help prevent the screw and prosthetic components from loosening.

(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)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992538