JUL 2 4 2014
K132749

1.4 510(k) Summary

Submitted by:	Phuong Nguyen Son Senior Regulatory Affairs Manager Nobel Biocare USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Submitted for:	Nobel Biocare AB Västra Hamngatan 1 Goteborg, SE 411 17 Sweden
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Date of Submission:	August 30, 2013
Classification Name: Product Code:	Endosseous Dental Implant Abutment (21 CFR 872.3630) NHA
Trade or Proprietary or Model Name:	NobelProcera Overdenture Bar
Legally Marketed Devices:	Procera® Implant Bridge Overdenture (K090069)

Device Description:
NobelProcera Overdenture Bars are computer aided design (CAM) precision milled, individually designed Superstructures manufactured for each patient. The NobelProcera Overdenture Bar provides retention and support for a removable or fixed denture made of standard laboratory dental materials such as resin composite or porcelain veneer.

The Superstructures can be either Fixed Shaped Bars such as Dolder, Hader, Round, or Free Form Shaped Bars such as Free Form Milled, Montreal, Paris, Wrap-around; or a combination of shapes. The Overdenture Bar shapes and design parameters remain unchanged from the predicate device, Procera Implant Bridge Overdenture (K090069). Additionally, the Superstructure can also be designed per specific prescription order by qualified health care professionals.

The Superstructure is a multiple unit restoration for fixed or removeable dental prosthetic framework milled from one solid piece of material. The NobelProcera Overdenture Bar accommodates commercially available denture attachments for removable dental prosthesis, or retention elements for fixed dental prosthesis.

The many abutment and implant interfaces that can be used in the Superstructure are precision milled and are an integral part of the Overdenture Bar.

The NobelProcera Overdenture Bar is packaged as non-sterile, and delivered to a dental laboratory for completion. Once received at the laboratory, the NobelProcera Overdenture Bar is matched to a denture for final placement.

Indications for Use:
The NobelProcera Overdenture Bar is indicated for use as an overdenture bar that attaches to implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

The NobelProcera Overdenture Bar is compatible with the below implants and abutments:

Manufacturer	Name	Sizes
3i® (BioMet)	(Certain) Internal	3.4, 3.75/4.0, 5.0, 6.0
	Conical Abutment	3.4, 4.1/5.0, 6.0
	External (hex)	3.4, 4.1, 5.0, 6.0
	IOL® Abutment	-
	Low Profile abutments	-
	Standard abutment	-
AB Dental Devices	Narrow Platform	-
Alpha Bio	Internal Hex	4.5
	TCT System	-
Anthogyr	Anthofit® HE System Conical Abutment	4.1
	Anthofit® OI System	3.5
	Anthofit® OI System Conical Abutment	3.5
	Axiom REG/PX Platform	4.0
	Axiom REG/PX Straight Conical Abutment	-
BEGO Semados®	S/RI-Line	3.25/3.75/4.1/4.5, 5.5
BioHorizons®	Abutment for Screw	3.5/4.0, 5.0
	Conical internal connection	3.0, 3.5, 4.5, 5.7
	External implant system	3.5, 4.0, 5.0, 6.0
	Single Stage Restoration	3.5, 4.5, 5.7
Biotech Dental Implants	B.I.S. Conic	3.5/3.9, 4.0/4.4, 5/5.4
	B.I.S. Conic Base Analog	4.4
BTI®	Externa® Platform (abutment level)	4.1
	Externa® Platform (implant level)	4.1
	Interna® Platform	4.1
	Tiny® Platform	3.5
Camlog®	Camlog Bar Abutment	3.3, 3.8, 6.0
	Camlog Implant System	3.3, 3.8, 4.3, 5.0, 6.0
	CONELOG Implant System	3.8
Dentsply (Ankylos®)	Balance Base Abutment	-
	Balance Base Abutment Narrow	-
	Balance Base C	-
	Regular C/X Abutment	-
Dentsply (Astra Tech®)	20° UniAbutment	3.5/4.0
	45° UniAbutment	3.5/4.0
	Astra ST	3.5
	Astra Tech	Yellow, Aqua, Lilac
Dentsply (XIVE®)	FRIADENT®	3.0, 3.4, 3.8, 4.5, 5.5
	FRIADENT® MP	3.8, 4.5, 5.5
	TG Platform	3.4-4.5
Hiossen	ET III SA	mini, regular
HI-TEC implants	Universal Unit System	-
Implant Direct	Attachment International	3.25, 3.3
	Legacy™	3.0, 3.5, 4.5, 5.7
	RePlant®/RePlus®	3.5, 4.3, 5.0
	ScrewIndirect	-
	ScrewIndirect	5.0

Manufacturer	Name	Sizes
	ScrewPlant®/ScrewPlus®	3.7, 4.7, 5.7
Implant Direct (Sybron)	Endopore® Internal Hex	4.1
	Entegra™ External Hex	3.5, 4.1, 5.0
	PITT-EASY® Paracentric Line	3.75, 4.0, 4.9
	SybronPRO™ Series Hex	3.5, 4.1
LifeCore Dental (Keystone)	Genesis System	3.8, 4.5, 5.5
	PrimaConnex® System	3.5, 4.1, 5.0/7.0/8.0
	PrimaConnex® System Multi-unit	3.5/4.1, WD
	Renova® Implant System	SDI 3.75, RDI 4.5
	Restore® Implant System	SD 3.3, RD 3.75/4.0, WD
	Stage-1 system RDS	-
MIS®	Internal Hex	-
	Multi-Unit system	-
	Standard Platform	-
	Wide Interial Hex	-
Neoss	Access Abutment	-
	Neoss Implant System	3.25
Nobel Biocare	Brånemark System (External Hex)	NP, RP, WP
	Hex	2.0
	Internal Hexagon	-
	Multi-Unit Abutment	NP/RP, WP
	Nobel Novum	-
	Nobel Replace (Internal Trilobe)	NP, RP, WP, 6.0
	NobelActive (Conical Connection)	NP, RP, WP
	Replace Hex Abutment	3.5, 4.3, 3.25HL, 3.8/4.5 HL, 5.0 HL, 6.0 HL
Osstem	TS & GS System	Mini 4.0, standard 4.5
	US System Esthetic Low	-
	US System Regular platform	-
SIC Implants	Sic Platform	3.3, 4.2
Simpler Implants	Implant Analog	3.25, 4.0
Southern Implants	External Hex	4.0, 5.0
Straumann®	Bone Level	3.3, 4.1/4.8
	Multi-base	NC 3.5, RC 4.5, RC 6.5
	Octagon	3.5, 4.8, 6.5
	Ortho System	4.2
	SynOcta®	RN, WN
Thommen Medical	SPI®RETAIN DIRECT System	-
	SPI®VARIOmulti System	4.0, 4.5, 5.0
	VARIOeco system	3.5, 4.0, 4.5, 5.0, 6.0
Titan implant	Internal Hex platform	4.5, 5.7
Zimmer® Dental	AdVent	4.5
	Calcitek	3.25, 4.0
	Screw-Vent	3.5, 4.5, 5.7
	Specta-Cone	-
	Spline® Implant System	3.25, 3.75/4.0, 5.0
	SwissPlus® Implant System	3.8, 4.8
	Tapered abutment	4.5

Summary of testing to demonstrate Substantial Equivalence

A retrospective study of NobelProcera Overdenture Bar placed in the market globally since 2010 was performed to establish the safety and effectiveness of the additional implant and abutment interfaces. The NobelProcera Overdenture Bar data set of compatible implant and abutment interfaces were generated through measurements of original manufacturer's bar interfaces. Additionally, non-clinical test data was used to demonstrate substantial equivalence. Non-clinical testing consisted of performance of fatigue testing in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

MR conditional testing was conducted according to FDA Guidance Document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment".

Comparison of Technological Characteristics

CHARACTERISTIC	CANDIDATE NobelProcera Overdenture Bar	PREDICATE Procera Implant Bridge Overdenture (K090069)
Trade Name	NobelProcera Overdenture Bar	Procera Implant Bridge Overdenture
Anatomical Site	Oral Cavity	Oral Cavity
Design/Construction	Patient specific / machined	Patient specific / machined
Device Material	Titanium alloy	Titanium alloy
Design Method Bar Order	Individually designed for each patient by order of prescription	Individually designed for each patient by order of prescription
Bar Shape	Fixed shaped bars Dolder, Hader, Round Free form shaped bars Milled, Montreal, Paris, Victoria, Wrap-around	Fixed shaped bars Dolder, Hader, Round Free form shaped bars Milled, Montreal, Paris, Victoria, Wrap-around
Platform Compatibility	See Indications for use statement'	Branemark System NP, RP, WP NobelReplace NP,RP, WP, 6.0 NobelActive NP, RP Multi-unit NP/RP, WP Astra Tech Yellow, Aqua, Lilac Straumman Octagon 3.5,4.8, 6.5 Straumman Bone Level 3.3, 4.1/4.8 BioMet 3i Internal 3.4, 3.75/4.0, 5.0, 6.0 BioMet 3i External 3.4, 4.1, 5.0, 6.0 Zimmer Screw-Vent 3.5, 4.5, 5.7 Zimmer AdVent 4.5

CHARACTERISTIC	CANDIDATE NobelProcera Overdenture Bar	PREDICATE Procera Implant Bridge Overdenture (K090069)
Ordering/Manufacturing Process	A master cast is received with the patient's impression. The Nobel Biocare's manufacturing facility scans the master cast to create the manufacturing files. Then the design files are compiled for CAM using a CNC milling system. The machined Overdenture bar is inspected for fit against the master cast. The overdenture bar is sent to the laboratory for verification of fit and integration with a denture.	Procera Implant bridges can be designed either using traditional wax-up technique or by using Nobel's Procera Software. When the wax-up technique is used, either the master cast or a scan of the master cast can be sent to Nobel for production. If the Procera Software is used, the design information is transmitted to Nobel for production. If necessary Nobel Biocare's manufacturing facility scans the master cast to create the manufacturing files. Then the design files are compiled for CAM using a CNC milling system. The machined overdenture bar is sent to the laboratory for verification and integration with a denture.
Overdenture Bar Implant/Abutment Interface	Nobel Biocare and additional manufacturers' implant and abutment interfaces	Nobel Biocare and other manufacturers' implant interfaces
Packaging	Plastic bag and cardboard box	Plastic bag and cardboard box
Sterility	Non-sterile	Non-sterile
Intended Use	Removable or fixed superstructure	Removable or fixed superstructure
Indications for Use	Compatible platforms added to indications for use.	The Procera Implant Bridge Overdenture is indicated for use as an overdenture bar that attaches to implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.
Labeling	MR Safety Information	No MR Safety information

Conclusion

The information provided in this submission demonstrates that the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 24, 2014

Nobel Biocare AB
C/O Ms. Phuong Nguyen Son
Senior Regulatory Affairs Manager
Nobel Biocare USA, Limited Liability Company
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Re: K132749
Trade/Device Name: NobelProcera Overdenture Bar
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 26, 2014
Received: June 26, 2014

Dear Ms. Son:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. 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,

Mary S. Runner -S FDA

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132749

Device Name: **NobelProcera Overdenture Bar**

Indications For Use:

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	Conical Abutment	3.4, 4.1/5.0, 6.0
	External (hex)	3.4, 4.1, 5.0, 6.0
	IOL® Abutment	-
	Low Profile abutments	-
	Standard abutment	-
AB Dental Devices	Narrow Platform	-
Alpha Bio	Internal Hex	4.5
	TCT System	-
Anthogyr	Anthofit® HE System Conical Abutment	4.1
	Anthofit® OI System	3.5
	Anthofit® OI System Conical Abutment	3.5
	Axiom REG/PX Platform	4.0
	Axiom REG/PX Straight Conical Abutment	-
BEGO Semados®	S/RI-Line	3.25/3.75/4.1/4.5, 5.5
BioHorizons®	Abutment for Screw	3.5/4.0, 5.0
	Conical internal connection	3.0, 3.5, 4.5, 5.7
	External implant system	3.5, 4.0, 5.0, 6.0
	Single Stage Restoration	3.5, 4.5, 5.7
Biotech Dental Implants	B.I.S. Conic	3.5/3.9, 4.0/4.4, 5/5.4
	B.I.S. Conic Base Analog	4.4

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Manufacturer	Name	Sizes
BTI®	Externa® Platform (abutment level)	4.1
	Externa® Platform (implant level)	4.1
	Interna® Platform	4.1
	Tiny® Platform	3.5
Camlog®	Camlog Bar Abutment	3.3, 3.8, 6.0
	Camlog Implant System	3.3, 3.8, 4.3, 5.0, 6.0
	CONELOG Implant System	3.8
Dentsply (Ankylos®)	Balance Base Abutment	-
	Balance Base Abutment Narrow	-
	Balance Base C	-
	Regular C/X Abutment	-
Dentsply (Astra Tech®)	20° UniAbutment	3.5/4.0
	45° UniAbutment	3.5/4.0
	Astra ST	3.5
	Astra Tech	Yellow, Aqua, Lilac
Dentsply (XIVE®)	FRIADENT®	3.0, 3.4, 3.8, 4.5, 5.5
	FRIADENT® MP	3.8, 4.5, 5.5
	TG Platform	3.4-4.5
Hiossen	ET III SA	mini, regular
HI-TEC Implants	Universal Unit System	-
Implant Direct	Attachment International	3.25, 3.3
	Legacy™	3.0, 3.5, 4.5, 5.7
	RePlant®/RePlus®	3.5, 4.3, 5.0
	ScrewIndirect	-
	ScrewIndirect	5.0
	ScrewPlant®/ScrewPlus®	3.7, 4.7, 5.7
Implant Direct (Sybron)	Endopore® Internal Hex	4.1
	Entegra™ External Hex	3.5, 4.1, 5.0
	PITT-EASY® Paracentric Line	3.75, 4.0, 4.9
	SybronPRO™ Series Hex	3.5, 4.1
LifeCore Dental (Keystone)	Genesis System	3.8, 4.5, 5.5
	PrimaConnex® System	3.5, 4.1, 5.0/7.0/8.0
	PrimaConnex® System Multi-unit	3.5/4.1; WD
	Renova® Implant System	SDI 3.75, RDI 4.5
	Restore® Implant System	SD 3.3, RD 3.75/4.0, WD
	Stage-1 system RDS	-
MIS®	Internal Hex	-
	Multi-Unit system	-
	Standard Platform	-
	Wide Internal Hex	-

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Manufacturer	Name	Sizes
Neoss	Access Abutment	-
	Neoss Implant System	3.25
Nobel Biocare	Brånemark System (External Hex)	NP, RP, WP
	Hex	2.0
	Internal Hexagon	-
	Multi-Unit Abutment	NP/RP, WP
	Nobel Novum	-
	Nobel Replace (Internal Trilobe)	NP, RP, WP, 6.0
	NobelActive (Conical Connection)	NP, RP, WP
	Replace Hex Abutment	3.5, 4.3, 3.25HL, 3.8/4.5 HL, 5.0 HL, 6.0 HL
Osstem	TS & GS System	Mini 4.0, standard 4.5
	US System Esthetic Low	-
	US System Regular platform	-
SIC Implants	Sic Platform	3.3, 4.2
Simpler Implants	Implant Analog	3.25, 4.0
Southern Implants	External Hex	4.0, 5.0
Straumann®	Bone Level	3.3, 4.1/4.8
	Multi-base	NC 3.5, RC 4.5, RC 6.5
	Octagon	3.5, 4.8, 6.5
	Ortho System	4.2
	SynOcta®	RN, WN
Thommen Medical	SPI®RETAIN DIRECT System	-
	SPI®VARIOmultI System	4.0, 4.5, 5.0
	VARIOeco system	3.5, 4.0, 4.5, 5.0, 6.0
Titan Implant	Internal Hex platform	4.5, 5.7
Zimmer® Dental	AdVent	4.5
	Calcitek	3.25, 4.0
	Screw-Vent	3.5, 4.5, 5.7
	Specta-Cone	-
	Spline® Implant System	3.25, 3.75/4.0, 5.0
	SwissPlus® Implant System	3.8, 4.8
	Tapered abutment	4.5

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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