



Food and Drug Administration
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January 15, 2016

Renovo Life LLC
% Mr. Donald Gunther
Regulatory Consultant
Orgenix LLC
111 Hill Road
Douglassville, Pennsylvania 19518

Re: K151661

Trade/Device Name: Renovo Life Hard Carbon Coated Drill Bit
Regulation Number: 21 CFR 888.4540
Regulation Name: Orthopedic Manual Surgical Instrument
Regulatory Class: I
Product Codes: HTW
Dated: December 5, 2015
Received: December 8, 2015

Dear Mr. Gunther:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151661

Device Name

Renovo Life Hard Carbon Coated Drill Bit

Indications for Use (Describe)

The Renovo Life Hard Carbon Coated Drill Bit is used to cut bone prior to insertion of bone screws or guide pins.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Manufacturer: Renovo Life LLC
1104 Spruce Street
Belmont, NC 28012

Date: January 14, 2016

Submitted by: Renovo Life LLC

Company Contact: Harold Crowder
+1(704) 224-4136
hcrowder@renovolife.com

Official Correspondent: Orgenix LLC
Mr. Donald W. Guthner
111 Hill Road
Douglassville, PA 19518
+1-646-460-2984
+1-484-363-5879 (FAX)
dg@orgenix.com

Proprietary Name: Renovo Life Hard Carbon Coated Drill Bit

Performance standards: The *Renovo Life Hard Carbon Coated Drill Bits* are made of surgical grade stainless steel conforming to ASTM F899.

Regulation: 21 CFR 888.4540

Common/Usual Name: Drill Bit

Classification name: Orthopedic manual surgical instrument

Review Panel: Orthopedic

Primary Product Code: HTW

Device Class: Class I

Substantial Equivalence: Substantial equivalence for the *Renovo Life Hard Carbon Coated Drill Bits* is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices.

Primary Predicate Device: Mahe Surgical Drill Bits (Class I)

Reference Device: K990846 Nobel Biocare Amorphous Diamond Coated Drill (Class II)
The subject device is substantially equivalent to similar previously cleared devices.

Device Description:

Renovo Life Hard Carbon Coated Drill Bits are available in diameters ranging from 1.1 mm to 8.0 mm, lengths ranging from 60 mm to 300 mm, and either solid or cannulated. The drill bits are designed with a standard connections.

Renovo Life Hard Carbon Coated Drill Bits are made of surgical grade stainless steel. The bone-cutting portion of the drill is coated with a hard carbon coating.

Renovo Life Hard Carbon Coated Drill Bits are provided non-sterile and are intended for single use only.

Indications for Use::

The *Renovo Life Hard Carbon Coated Drill Bit* is used to cut bone prior to insertion of bone screws or guide pins.

Common use of drill bits:

Drill bits are intended for use in the drilling of bone and other bone-related tissue in a variety of surgical procedures. Procedures for use on bone are often used in orthopedic, dental, oral surgery, maxillofacial, plastics, ENT, and neurological surgeries. Drill bits are also used in the placement of screws, wires, pins, and other fixation devices.

The *Renovo Life Hard Carbon Coated Drill Bits* are designed to drill holes in bones

Non-Clinical Testing

The *Renovo Life Hard Carbon Coated Drill Bits* have undergone mechanical testing to show substantial equivalence to the predicate device.

A comprehensive series of tests were conducted on the *Renovo Life* drill bits coated with a hard carbon coating (manufactured by BioMedFlex LLC.). Testing was performed on uncoated, coated, and aged coated *Renovo Life* drill bits. The test results were analyzed and are summarized in the body of this report to determine if the coating provided an adequate interface for drilling bone and demonstrated reduced heating and improved resistance to fatigue (longevity). Table 1 outlines the series of tests conducted on the coated drill bit to assess biocompatibility and mechanical integrity of the coating.

TABLE 1: - SUMMARY OF TESTS AND ANALYSES CONDUCTED

TEST METHOD	TEST STANDARDS
Biocompatibility ISO 10993	
Cytotoxicity	ISO 10993
Maximization Sensitization	ISO 10993
Intracutaneous Study	ISO 10993
Systemic Toxicity	ISO 10993
Steam Sterilization – Part I	ANSI/AAMI/ISO 17665-1:2006 (EN ISO 17665-1:2006)
Steam Sterilization – Part II	ANSI/AAMI/ISO 17665-1:2006 (EN ISO 17665-1:2006)
Accelerated Aging – 1 year	ASTM F1980-07
Mechanical Integrity of Coating –	No Standards for this test
Wear surface Analysis of Drill Bits	ASTM F1877 - guideline for methods and comparison

Clinical
Testing
Comparison
Table

No clinical testing was performed.

Information	Subject Device	Primary Predicate	Reference Device
Manufacturer	Renovo Life LLC	Mahe Medical	Nobel Biocare
Trade Name	Renovo Life Hard Carbon Coated Drill Bits	Mahe Surgical Drill Bits	Amorphous Diamond Coated Drill Bits
510(k) Number	K151661	N/A (Class I)	K990846
Product Code	HTW	HTW	DZI
Classification	888.4540	888.4540	872.4120
Materials	Stainless Steel Hard Carbon Coating	Stainless Steel	Stainless Steel Amorphous Diamond
Indications for Use	The <i>Renovo Life Hard Carbon Coated Drill Bit</i> is used to cut bone prior to insertion of bone screws or guide pins	Drill Bits are used to cut bone prior to insertion of bone screws or guide pins	The drill is used to cut into the maxilla or mandible to create an osteotomy for endosseous dental implant placement.
Design	Standard square head	Standard square head	Latch end to use with hand piece
Diameters	1.1 to 8.0 mm	1.1 to 8.0 mm	2.0 mm
Lengths	60 to 300 mm	60 to 300 mm	18 mm
Styles	Solid, Cannulated	Solid, Cannulated	
Cutting Flutes	Two	Two	Three
Sterility	Non-sterile	Non-sterile	Non-sterile
Packaging	Plastic bag	Plastic Bag	Plastic vial with foam inserts

Substantial equivalence for the *Renovo Life Hard Carbon Coated Drill Bits* is based on its similarities in indications for use, design features, operational

principles and material composition when compared to the primary and reference predicate devices:

1. Mahe Surgical Drill Bits (Class I)

Substantial equivalence for the *Renovo Life Hard Carbon Coated Drill Bits* is based on its similarities in material composition when compared to the reference device:

2. Nobel Biocare Amorphous Diamond Coated Drill (K990846)

A search of the MDR and MAUDE databases showed no reported incidences with these materials for this indication, indicating a certain level of performance of the product.

Thus, the *Renovo Life Hard Carbon Coated Drill Bits* are substantially equivalent to the predicate devices.