



Food and Drug Administration
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Silver Spring, MD 20993-0002

April 8, 2016

Noris Medical Ltd.
Ms. Simha Sibony
VP Regulatory Science
8 Hataasia St.
Nesher, 3688808
ISRAEL

Re: K151909

Trade/Device Name: Noris Medical Zygomatic Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 1, 2016
Received: March 9, 2016

Dear Ms. Sibony:

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,



Tina Kiang -S

for 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)

K151909

Device Name

Noris Medical Zygomatic Dental Implant System

Indications for Use (Describe)

Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.

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.

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K151909
510(k) Summary

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Noris Medical Zygomatic Dental Implant System

1. GENERAL INFORMATION

Date Prepared:	April 7, 2016
	Noris Medical Zygomatic Dental Implant System
Common Name:	Endosseous Dental Implant
Classification Name:	Implant, Endosseous, Root-Form
Class:	II
Product Code:	DZE/NHA
CFR section:	21 CFR§872.3640
Device panel:	Dental
Legally Marketed Predicate Device:	Primary Predicate: K093562-SOUTHERN IMPLANTS Inc. K140440-Noris Medical Ltd.
Submitter:	Noris Medical Ltd. 8 Hataasia street, Neshar 3688808, Israel
Contact 1:	Ms. Simha Sibony- VP Regulatory Science Noris Medical Ltd 8 Hataasia St., Neshar 3688808 ISRAEL M: +972 52-654-6625 T: +972 (73) 796-4477 F: +972 (4) 695-0991 E: simhas@norismedical.com
Contact 2:	Mr. Aharon Siev, President Noris Medical Ltd 8 Hataasia St. Neshar 3688808 ISRAEL T: +972(73)796-4477 F: +972(4)695-0991 E: asiev@norismedical.com

2. DEVICE DESCRIPTION

2.1. BACKGROUND - *Noris Medical Dental Implants* are tapered internal hex implants, designed to enable easy insertion while supporting excellent initial stability. The variable thread design enables self-tapping, thus providing

solutions for a variety of bone conditions. Noris Medical multi-design features offer a solution for immediate placement and immediate loading. The implantation procedure can be accomplished in a one-stage or two-stage surgical operation for all implants type beside the Mono(Noris Medical cleared K140440) which is for one stage only. Packaging has been designed for quick identification and easy opening.

The scope of this submission is the following items:

2.2 NORIS MEDICAL ZYGOMATIC DENTAL IMPLANT

The Noris Medical Zygomatic Dental Implant is designed to provide a solution for cases of atrophic maxilla. The shape of the Noris Medical Zygomatic Dental Implant consists of sharp threads at the apical part. The platform of the Noris Medical Zygomatic Dental Implant is 3.75mm platform, with internal Hex connection. The Noris Medical Zygomatic Dental Implant is available in a large variety of lengths, from 30 mm to 57.5 mm.

Zygomatic Implant sizes and dimensions:

	<p>Diameter : 4.2, mm Length 30, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5 mm Made of titanium alloy Ti 6Al 4V ELI</p>
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2.3 PROSTHETIC COMPONENTS FOR NORIS MEDICAL ZYGOMATIC IMPLANT

Background: Straight, 17°, 30° Multi unit and Vari connect prosthetic system are already cleared under previous Noris Medical 510k submission – K140440

Multi unit and Vari connect 45° prosthetic system are subject of this current submission as a part of the Zygomatic Dental Implant System.

Multi-Unit - screw retained reconstruction

The Multi-Unit system provides a solution for screw-retained prostheses even on complicated-to-restore implants (for example, multiple tilted implants). The Multi-Unit system comprises a full range of sizes for both the upper and lower jaws. Straight, 17°, 30°, 45° components, in a variety of heights, connects to a wide range of complementary products.

	<p>Angulated 45° - Length 4 mm Made of titanium alloy Ti 6Al 4V ELI</p>
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Vari-Connect - screw retained or removable reconstruction

The Vari-Connect system presents a complete solution for removable prostheses on tilted implants. It provides all the required equipment for removable prostheses, both on ball attachments and flat attachments, covering a wide range of possible situations. Straight, 17°, 30°, 45° components are available. Complementary products are fixed to the adaptors by the adaptor thread.

	<p>Angulated 45° - Length 4 mm Made of titanium alloy Ti 6Al 4V ELI</p>
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Materials and Production:

The implants and prosthetic components are manufactured from Titanium alloy complying with standard ASTM F 136 Standard *Specification for*

Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for surgical implant applications.

Noris Medical employs the RBM (Resorbable Blast Media) surface treatment technology.

The product is packed using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of 10^{-6} validated in compliance with ANSI/AAMI/ISO 11137-1 *Sterilization of healthcare products -- Radiation -- Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices.*

3. INTENDED USE

Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.

4. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

Identification of the Legally Marketed Predicate Devices Used to Claim Substantial Equivalence:

Noris Medical Zygomatic Dental Implant System is substantially equivalent to Primary predicate -Southern Implants Zygomatic Implant (K093562) in terms of intended use, design, materials used and performance testing. As well as to secondary predicate - Noris Medical Dental Implant System(K140440) in terms of Internal Hex connection, packaging and sterilization.

With regards to the intended use, material, design, characteristics and dimensions, the equivalence was determined through the points in following table:

Device Name	Southern Implants Zygomatic Implant (Primary Predicate)	Noris Medical Dental Implants system	Noris Medical Zygomatic Dental Implant System (Current Submission)
510k	K093562	K140440	K151909
Intended use	[1]	[2]	[3]
Patient Population	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals
Material	Titanium Grade 4	Titanium alloy	Titanium alloy
Diameter(mm)	4.05	Tuff Implant 3.3,3.75,4.2,5,6	4.2
Length(mm)	35, 40, 42.5, 45, 47.5, 50, 52.5, 55	Tuff Implant Series: 6,8,10,11.5,13,16	35,37.5,40,42.5,45,47.5, 50,52.5,55,57.5
Abutments°	55	0,15,17,25,30	45
Surface treatment	Machined, Oxidized surface	Sand blasted Acid-etched	RBM(Resorbable Blast Media)
Thread Design	Screw type	Tapered screw type	Tapered screw type
Sterility	Gamma irradiation	Gamma irradiation	Gamma irradiation
Clinical procedure	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period

[1] The Zygomatic implant is intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in partially edentulous or full arch prostheses. It further adds the option for immediate function when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. This implant is not intended, nor should it be used, in conjunction with an angled abutment.

[2] NORIS Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Mono implants are specifically indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. They are used for immediate, non-occlusal provisionalization in single-tooth restorations. Multiple-unit restorations should be splinted together and may be used immediately when clinically appropriate.

[3] **NORIS Medical** Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.

Evidence of equivalence has been demonstrated through the following:

- * The Noris Medical Zygomatic Dental Implant System's intended use and indications for use were previously cleared by FDA for the predicate devices.

- * The technical characteristics of the Noris Medical Dental implant System are similar to those of the predicate devices.

- * Nonclinical testing results for the Noris Medical Zygomatic Dental implants System are similar to those of the predicate devices.

Therefore, the Noris Medical Zygomatic Dental Implant System is substantially equivalent to the predicate devices in terms of intended use, materials used, and technological characteristics

4. NON-CLINICAL TESTING

The Noris Medical Zygomatic Dental Implant is manufactured from medical grade Titanium alloy per ASTM F136.

SEM and Surface analysis (EDS) after RBM process demonstrated the morphology and cleanliness of the final product.

Sterilization validation tests for the Noris Medical Dental Implants System were conducted in compliance with the following:

- ANSI/AAMI/ISO 11137-1:06 and EN ISO 11137-2:12 and ANSI/AAMI ST79:2010 & A1:2010.

Biocompatibility tests were conducted in compliance with the following:

- AAMI ANSI ISO 10993-5: 2009 (R)2014 - Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- AAMI ANSI ISO 10993-11: 2006 (R)2010 - Biological evaluation of medical devices Part 11: Tests for systemic toxicity

Accelerated aging per ASTM-F-1980:07 has been applied on the final packaging followed by validating durability to peel, dye and burst tests conditions, in order to substantiate 5 years shelf life.

Static and dynamic compression performance testing was conducted per ISO 14801: 07- Dentistry-Implants-Dynamic fatigue test for Endosseous Dental implants.

The worst case scenario was chosen based on the FDA guideline "Class II Special Controls Guidance Document: Root form for Endosseous dental implants and Endosseous dental Implant Abutments".

Comparative testing was conducted according to a modified ISO 14801 set-up to account for the nominal bone level for a zygomatic dental implant design

The results of the testing indicate that the Noris Medical Zygomatic Dental Implant is substantial equivalent to the predicate devices cited in this submission.

5. CLINICAL EVALUATION

Because the subject device design represented a new technology, featuring a different threading pattern from its primary predicate, clinical testing was requested. The sponsor provided a series of retrospective, randomized clinical case studies to support the proposed device. The device was implanted in 18 patients (a total of 29 Zygomatic implants). All patients required dental extraction and immediate subject device implant replacement. The location for Zygomatic implant was usually in the upper second premolar.

The implants were placed during the years 2013 to 2014 in one clinical site in Israel, and in all 29 cases, immediate occlusal loading was employed. Patients were evaluated at a minimum of 6 months post-surgery, with the success endpoint identified as osseointegration following implant placement. Computed Tomography (CT) was taken Pre-op. Panoramic radiographs were taken Pre-op, immediately after implantation and after at least 6 month follow up.

In the clinical study report, the sponsor presented long-term results of several patients implanted with the subject device. A success rate of 96% was obtained after at least 6 months follow up. Those results correspond to the CSR (Cumulative Success Rate) reported worldwide by the sponsor for Zygomatic dental implants.

6. CONCLUSION

The results of the testing conducted on the Noris Medical Zygomatic Dental Implant System demonstrated that the system is substantially equivalent to the predicate devices in terms of functional, mechanical properties, indications for use and material.