February 4, 2022

Noris Medical Ltd
Simha Sibony
QA/RA
8 Hataasia
Nesher, 3688808
ISRAEL

Re: K210356
Trade/Device Name: Noris Medical Dental Implants System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 2, 2022
Received: January 5, 2022

Dear Simha 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210356

Device Name
Noris Medical Dental Implants 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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NORIS Medical®
Dental Implant Solutions

K210356

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 Dental Implants System

1. GENERAL INFORMATION

Date Prepared:	February 4, 2022
Trade/Device Name:	Noris Medical Dental Implants System
Common Name:	Endosseous Dental Implant Abutment
Classification Name:	Abutment, Implant, Dental, Endosseous
Class:	II
Product Code:	NHA
CFR section:	21 CFR§872.3630
Device panel:	Dental Device Panel
Legally Marketed Primary Predicate Device:	K151909 – Noris Medical Ltd
Legally Marketed Reference Devices:	K140440 – Noris Medical Ltd K161598-Nobel Biocare A B
Submitter:	Noris Medical Ltd. 8 Hataasia street, Nesher 3688808, Israel
Contact 1:	Ms. Simha Sibony- Regulatory Affairs Consultant – GMRE Ltd RA/QA Consultant M: +972 52-654-6625 T: +972 (73) 796-4477 F: +972 (4) 695-0991 E:simhasibony@gmail.com
Contact 2:	Mr. Udi Dailes – VP Executive Noris Medical Ltd 8 Hataasia St. Nesher 3688808 ISRAEL T: +972(54)2626719 F: +972(4)695-0991 E: udid@norismedical.com

2. DEVICE DESCRIPTION

2.1 NORIS MEDICAL MULTI UNIT AND VARI CONNECT ABUTMENTS

Background:

Multi Unit, Vari Connect 52° and 60° 2mm height prosthetic system are subject of this current submission as a part of the Dental Implants System (K151909).

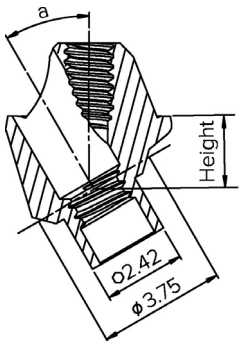
Multi Unit 17°, 30°, (K140440) with additional 4, 5 mm gingival height are subject of this current submission.

Vari Connect 17°, 30° (K140440) with additional 4, 5, 6 mm gingival heights are subject to this current submission.

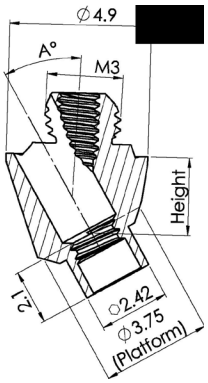
Multi Unit 45°(K151909) with additional 4, 5 mm gingival height are subject of this current submission.
Vari Connect 45°(K151909) with additional 4,5,6 mm gingival heights are subject to this current submission.

Illustration of Gingival Height:

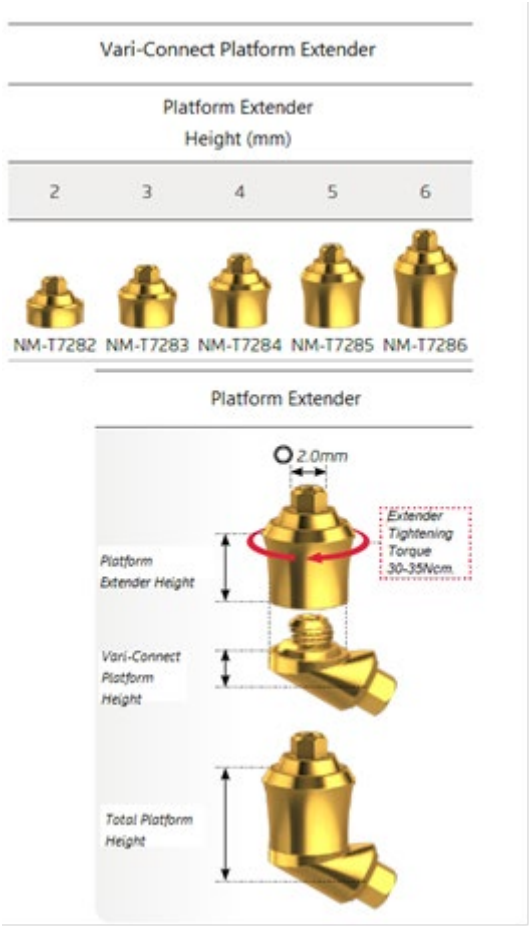
Multi Unit



Vari Connect



Vari Connect Extender



By adding the extenders to Vari Connect 2mm height, the final heights of 4, 5,6,7,8 mm will be obtained.

The system also includes abutment fixation screws.

Noris Medical Multi Unit and Vari Connect 45°, 52°, 60° abutments are intended to be used only with Noris Medical Zygomatic Dental implant (K151909).

Noris Medical Multi Unit and Vari Connect 17°, 30° abutments are intended to be used only with Noris Medical Dental implants System(K140440).

2.2.1 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.

2.2.2 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. Complementary products: Vari Connect extenders are fixed to the Vari Connect abutment by the extender's thread.

ANGLED MULTI-UNIT

Angled Multi-Units

Multi-Unit Platform Height (mm)

Angle°	2	3	4	5
17°	NM-A7112	NM-A7113	NM-A7114	NM-A7115
30°	NM-A7133	NM-A7134	NM-A7135	NM-A7136
45°	NM-A7144	NM-A7145	NM-A7146	NM-A7147
52°	NM-A7152			
60°	NM-A7160			

Included with all multi-unit bases

NM-S7101

Abutment Cary-on handle
NM-X7101

ANGLED VARI-CONNECT

Angle Vari-Connect

Vari-Connect Platform Height (mm)

Angle°	2	3
17°	NM-A7212	NM-A7213
30°	NM-A7233	NM-A7234
45°	NM-A7244	
52°	NM-A7252	
60°	NM-A7260	

3. 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.* Abutments are anodized gold, the same as the reference device K140440.

4. 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.

5. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

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

Noris Medical Multi Unit and Vari Connect 52°,60° abutments subject to this submission are substantially equivalent to **Primary predicate** – Noris Medical Dental Implant System (K151909) in terms of intended use, design, and materials used.

Reference Device - Nobel Biocare K161598 Multi Unit 60° abutment connected to Zygomatic implant 50 mm-NobelZygoma 0° is equivalent to current submission in terms of performance testing. **Reference Device** Noris Medical Dental Implant System (K140440) is equivalent to current submission in terms of similar 3.75 mm Platform and Internal Hex connection for all abutments components connected to the same Noris Medical Dental implants system.

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

Table 1: Comparison of subject and predicate abutments characteristics (K151909)

	Nobel Biocare **Multi Unit 60° abutment** **Reference Device**	**Noris Medical** **Zygomatic Dental Implant System-** **Primary Predicate** **Multi Unit/Variconnect**	**Noris Medical** **Dental Implant System-** **Current Submission** **Multi Unit/Variconnect** **Connected to Noris Zygomatic Dental Implant system K151909 only**	**Equivalence Discussion**
510k	K161598	K151909	Current Submission	-
Indication for use	[3]	[2]	[4]	Identical Same indication for use for subject and primary predicate
Patient Population	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Identical
Material **abutments**	Titanium alloy	Titanium alloy	Titanium alloy	Identical Subject and predicate devices have the same material of construction.

Abutments°	45,60	45	45,52,60	SE the angulation is equivalent to the reference device
Abutment Gingival Height-mm	45°: 6mm, 8mm, 10mm 60°: 6mm,8mm	2 mm	Multi Unit 45°: 3,4,5 mm Variconnect 45° extender: 3,4,5,6 mm 52°,60°: 2 mm	SE: The subject device is equivalent to reference device. Dynamic fatigue test of the subject device shows equivalent performance in comparison to predicate device See Section 6.3
Screw material	Titanium alloy	Titanium alloy	Titanium alloy	Identical
Compatible implant abutment	External Hex Regular Platform (RP)	Internal Hex 3.75mm platform	Internal Hex 3.75mm platform	Identical to predicate device
Sterility	Supplied sterile Single use	Supplied non-sterile. Single use Steam sterilized before use	Supplied non-sterile. Single use Steam sterilized before use	Identical to primary predicate device

Table 2: Comparison of subject and predicate abutments characteristics (K140440)

	Noris Medical Dental Implants system- Reference Device	**Noris Medical Dental Implants System- Current Submission Multi Unit/Variconnect Connected to Noris Medical Dental implants K140440 only**	**Equivalence Discussion: Identical/SE**
510k	K140440	Current Submission	-
Intended use	[1]	[4]	Identical Same indication for use for subject and primary predicate
Patient Population	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Identical
Material abutments	Titanium alloy	Titanium alloy	Identical Subject and predicate devices have the same material of construction

Abutments°	0,15,17,25,30	Multi Unit/Variconnect 17,30	Identical the angulation is equivalent to the primary predicate device
Abutment Gingival Height-mm	Multi Unit 17,30°: 2,3 mm Variconnect 17,30°: 2mm	Multi Unit 17,30°: 4,5 mm Variconnect 17°,30° extender: 2,3,4,5,6 mm	SE : The subject device has additional gingival Height. Worst cases calculations for Multi unit with higher angulations show equivalent performance in comparison to their primary predicate device See Section 6.3
Screw material	Titanium alloy	Titanium alloy	Identical
Compatible implant abutment	Internal Hex 3.75mm platform	Internal Hex 3.75mm platform	Identical Subject and primary predicate devices are compatible with the same devices.
Sterility	Supplied non-sterile. Single use Steam sterilized before use	Supplied non-sterile. Single use Steam sterilized before use	Identical to primary predicate device

[1] **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.

[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. 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.

[3] Nobel Zygoma implants are endosseous implants intended to be surgically placed in the bone of the upper jaw arch to provide support for the prosthetic devices, such artificial teeth, in order to restore patient esthetics and chewing function. The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

[4] **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.

Evidence of equivalence has been demonstrated through:
* The Noris Medical Dental Implants System intended use and indications for use are similar to previously cleared FDA cleared predicate and reference devices.
* The technical characteristics of the Noris Medical Dental implants System are similar to those of the predicate and reference devices.
* Clinical and non-clinical performance testing results of the Noris Medical Dental implants System are similar to those of the predicate and reference devices.

Therefore, the Noris Medical Dental Implants System is substantially equivalent to the predicate device in terms of intended use, materials used, and technological characteristic

6. NON-CLINICAL TEST

6.1 **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
6.2 **Sterilization**
Sterilization validation for subject devices was conducted according to ISO 17665-1, ISO 17665-2, and ANSI/AAMI ST79.
6.3 **Mechanical tests**

Comparative fatigue testing was performed on both zygomatic predicate systems as well as the subject devices, following a modified ISO 14801 approach to reflect the extra-maxillary surgical techniques of the subject and predicate systems, utilizing worst-case constructs for each system

7. CLINICAL DATA

Real-world evidence of Nobel Biocare Zygomatic implant system cases were provided from the literature to address the clinical concerns regarding the worst case angulation 60° Multi Unit abutment subject to this submission in comparison to legally marketed Nobel Biocare Multi Unit 60°

Nobel Biocare Multi Unit (predicate device) presented in Ref. 1 below is provided as real world evidence data: A retrospective study including a total of 44 completely edentulous maxillary rehabilitations (77 Multi unit abutments) were performed.

The zygomatic implants used in this study were NobelZygoma 0_ with a TiUnite surface (Nobel Biocare AB, Göteborg, Sweden), and typically emerged between the first premolar and the first molar on the residual crest of the ridge, near its center).The study abutments were 45 and 60_Multi-unit abutments External Hex RP6 mm of height. The surgical protocol followed previous indications for zygomatic implants inserted through the extramaxillary surgical technique.
This implant is the predicate device presented in this current submission and the extramaxillary surgical technique is the same as Noris Medical surgical technique for Zygomatic implants.

Outcome Measures

Outcome measures were evaluated at implant surgery and at 2 years post-surgery.

The primary outcome measures were prosthetic success, implant success, abutment success and complications. modified plaque index (mPLI), modified bleeding index (mBI), mucosal seal efficacy evaluation (MSEE) >4 mm, and Zygomatic implants classification level (ZICL).Prosthetic success was judged in terms of function, being considered a failure if need to be replaced by a new prosthesis. Two patients (4.5%) were lost to follow-up. No prosthesis was lost; one patient lost one zygomatic implant; two angulated abutments of 60 degrees needed to be replaced in one patient due to an aesthetic complaint; rendering a cumulative success rate at 2-years of 95.3% and 95.9% using patient and implant/abutment as unit of analysis, respectively.

Table 3: Summary of clinical cases of Nobel Biocare Zygomatic/ Multi Unit system

(a)

Time (Months)	Status (0 = Success; 1 = Failure *)	Cumulative Proportion Success at the Time		N of Cumulative Events	N of Patients at Risk
		Estimate	Std. Error		
0	0			0	44
7	1	0.977	0.022	1	43
9	0			1	42
10	0			1	41
12	0			1	41
13	0			1	40
24	0			1	40

(b)

Duration	Total	Failed	Lost to Follow-Up	Censored	Survival Rate %	Cumulative Survival Rate %
Placement—1 year	77	1	1	5	98.7%	98.7%
1 year—2 years	70	0	2	2	100%	98.7%
2 years—3 years	52	0	0	25	100%	98.7%

* Failure was defined as the first implant to fail in one patient.

Citation:

Ref. 1 : *Angulated Abutments for Full-Arch Rehabilitation of Extremely Atrophic Maxillae: Short-Term Outcome of a Retrospective Cohort* - Armando L, Miguel de Araújo Nobre, Ana Ferro, Carlos Moura Guede, Ricardo Almeida and Mariana Nunes , J. Clin. Med. **2021**, 10, 3600

Noris Medical Multi Unit (subject device) clinical cases report was submitted.

This Noris Medical retrospective study included 33 patients (19 females and 14 males) with 88 Multi Unit abutment. The patients were on average 61 (36–86) years old. Patients required dental extraction and immediate replacement.

The implants were placed during the years 2013 to 2020. Patients were treated with Multi Unit abutments.

Panoramic radiographs and CT were taken Pre-op and Panoramic radiographs immediately after implantation and after at least 6 months follow up.

In this report 33 patients (88 Multi unit abutments) showed success relative to stability and no micro movements, no bleeding or soft tissue downgrowth, no pain was observed. Table 4 below provides a summary of the cases demonstrating that Noris Medical Zygomatic implant/MU abutment survival was 100 %(No failures). To evaluate the performance and local effects of implantation, 10 patients representing 14 clinical cases of Noris Medical Zygomatic implants system were provided to address concerns regarding the worst case angulation 60° Multi Unit abutment subject to this submission. Of the 33 patients noted, 10 used the 60° abutment.

Table 4: Summary of clinical cases of Noris Medical Zygomatic/Multi Unit System

Case no.	Gender	Age [years]	Position	Catalog number	Follow-up period [month]	Angle of Multi Unit	Status (0=Success; 1=Failure)
1	F	79	4, 2, 13	NM-A7144	8	45°	0
2	F	53	4, 2, 13, 15	NM-A7144	9	45°	0
3	F	52	2, 13, 15	NM-A7144	11	45°	0
4	F	65	4, 2, 13, 15	NM-A7144	13	45°	0
5	M	52	2, 13, 15	NM-A7144	8	45°	0
6	F	56	4, 2, 13, 15	NM-A7144	17	45°	0
7	F	64	4, 2, 13,15	NM-A7144	7	45°	0
8	M	71	4, 13	NM-A7144	11	45°	0
9	M	58	4, 2, 13, 15	NM-A7144	10	45°	0
10	M	51	2, 13, 15	NM-A7144	14	45°	0
11	M	68	4, 2, 15	NM-A7144	13	45°	0
12	F	55	2, 13, 15	NM-A7144	8	45°	0
13	M	64	4, 2, 13, 15	NM-A7144	11	45°	0
14	M	80	4, 2, 13, 15	NM-A7144	10	45°	0
15	F	60	4, 2, 13, 15	NM-A7144	10	45°	0
16	F	36	2, 13	NM-A7144	6	45°	0
17	F	52	2, 15	NM-A7144	7	45°	0
18	F	43	15	NM-A7144	7	45°	0
19	M	43	2	NM-A7144	7	45°	0
20	F	58	15	NM-A7144	6	45°	0
21	M	45	15	NM-A7144	8	45°	0

22	M	66	4	NM-A7144	11	45°	0
23	F	67	6	NM-A7152	13	52°	0
24	F	61	3, 14	NM-A7145	47	45°	0
24	F	61	6	NM-A7152	47	52°	0
24	F	61	11	NM-A7160	47	60°	0
25	F	86	4, 2,13,15	NM-A7145	11	45°	0
25	F	86	7	NM-A7160	11	60°	0
26	M	43	3, 14	NM-A7152	48	52°	0
26	M	43	6, 11	NM-A7160	48	60°	0
27	M	72	3	NM-A7160	13	60°	0
28	F	68	6, 11	NM-A7160	12	60°	0
29	F	67	4	NM-A7160	13	60°	0
30	M	78	6, 11	NM-A7160	15	60°	0
31	M	81	6, 4	NM-A7160	12	60°	0
32	F	81	11	NM-A7160	14	60°	0
33	F	79	6	NM-A7160	14	60°	0
33	F	79	4, 11,14	NM-A7144	14	45°	0

Conclusion:

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The Nobel Biocare MU cases presented in this report (real world evidence data –see ref.1 above) demonstrated substantially equivalent success of the predicate Device

All the Noris Medical MU cases presented in the submitted cases report demonstrate substantial equivalence results compared to Nobel Biocare predicate device in term of status of success.

Table 5 below details the Number of different Multi Unit angles that is included in the Noris Medical cases report and in the Nobel Biocare real world evidence clinical data.

Table 5: No. of MU abutment Cases- Noris Medical vs Nobel Biocare

Multi-unit Angle (degrees)	No. of abutments used – Noris Medical	No. of abutments used –Nobel Biocare
45	70	31
52	4	-
60	14	46
Total:	88	77

No adverse events nor inflammation were reported and the follow up showed 100% success of the Noris Medical MU abutment by attaining the end point of continuous stability of implant with no inflammation after at least 6 months.

Survival Rate of the 60° Zygomatic implant/abutment system Noris Medical was 100% vs Nobel Biocare was 93.5% within 6 months to 48 months Follow up and 24 months Follow up respectively.

8. CONCLUSION

The data presented in this submission demonstrates that the subject devices are substantially equivalent with respect to performance and intended use. The proposed devices perform as well as the legally marketed primary and reference devices.

The subject device, the primary predicate device, and the reference device have the same intended use, have similar technological characteristics. The subject device and the primary predicate, are made of identical materials, are packaged in the same materials, and are sterilized using the same methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Furthermore, the subject devices do not pose any new or increased risks as compared to the legally marketed predicate devices listed above.