



June 24, 2022

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

Re: K210852

Trade/Device Name: Noris Medical Dental Implants System - Cortical  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: DZE  
Dated: May 18, 2022  
Received: May 25, 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](mailto: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

## Indications for Use

510(k) Number (if known)

K210852

Device Name

Noris Medical Dental Implants System -Cortical

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.

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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## 510(k) Summary- K210852

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 Implant System- Cortical

### 1. GENERAL INFORMATION

<b>Date Prepared:</b>	June 24, 2022
	Noris Medical Dental Implants System - Cortical
<b>Common Name:</b>	Endosseous dental implant
<b>Classification Name:</b>	Implant, Endosseous, Root-Form
<b>Class:</b>	II
<b>Product Code:</b>	DZE
<b>CFR section:</b>	21 CFR 872.3640
<b>Device panel:</b>	Dental
<b>Legally Marketed Predicate Device:</b>	K140440 – Noris Medical Ltd
<b>Legally Marketed Reference Devices:</b>	K140091 MegaGen Implant Co., Ltd., K200586 Straumann USA, LLC; K151909-Noris Medical Ltd
<b>Submitter:</b>	Noris Medical Ltd. 8 Hataasia street, Nesher 3688808, Israel
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<b>Contact 2:</b>	Mr. Udi Dailes – VP Executive Noris Medical Ltd 8 Hataasia St. Nesher 3688808 ISRAEL T: +972(54)2626719 F: +972(4)695-0991 E: <a href="mailto:udid@norismedical.com">udid@norismedical.com</a>


## 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. Packaging has been designed for quick identification and easy opening. (Noris Medical cleared K140440).

The scope of this submission is Noris Medical Cortical Implant as part of the Noris Medical dental Implants system identical platform.

### 2.2. NORIS MEDICAL CORTICAL IMPLANTS

Cortical implants are able to undergo immediate loading when good primary stability is achieved and with appropriate occlusal loading. The Cortical system can be used in extraction sites for immediate implantation. Cortical implant is available in different sizes to suit relevant implantation site.

	<b>Cortical – NM-MXXXX</b>	
	Diameter 4.0 mm	Length 11.5, 13, 16, 18, 20 mm
	Diameter 5.0 mm	Length 11.5, 13, 16 mm
	Diameter 6.0 mm	Length 11.5, 13, 16 mm
Made of titanium alloy Ti 6Al 4V ELI		

## 3. INDICATION FOR 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.

#### **4. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES**

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

**Predicate device:** K140440 – Noris Medical Ltd – TUFF implant with regards to intended use, material, platform internal Hex design, packaging and sterilization.

**Reference predicate device:** K151909-Noris Medical Ltd with regards to RBM surface treatment

**Reference predicate device 1:** K140091 MegaGen Implant Co., Ltd. with regards to threads design.

**Reference predicate device 2:** K200586 Straumann USA, LLC with regards to neck implant design.

#### **5. Summary of similarities and differences (See Table 1 and Fig.1 below)**

##### **Indications for Use:**

[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.

[2] **The Xpeed AnyRidge** Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.

[3] **Straumann TLX Implants** are suitable for endosteal implantation in the upper and lower jaws and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. TLX Implants can be placed with immediate function on single-tooth multi-unit restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment component.

## 5.1 Similarities

The subject device has the followings same/equivalent characteristic for the compared to the predicate device (Noris TUFF K140440):

Indication for use, Internal Connection, Single Use, Material, Sterilization and Shelf Life.

The subject device has the followings same/equivalent characteristic for the compared to the **reference 1** (Megagen AnyRidge K140091):

Indication for use, Design of threads, Internal Connection, Single Use, Sterilization.

The subject device has the followings same/equivalent characteristic for the compared to the **reference 2** (Straumann TLX K200586):

Indication for use, Design shape (gingival section), Type (Tissue Level), Single Use, Sterilization.

The diameter and length of subject device lies in the range of all predicate and reference devices.

## 5.2 Differences

The subject device has the different characteristic for the followings compared to the predicate and reference devices:

### 1) Gingival (Cuff)

The subject device is different from predicate and Ref 1 devices since the subject device is Tissue level design and the others are Bone level design implants.

### Gingival (Cuff) Height (compared only to Ref 2)

The subject device has cuff height 4mm with consideration for soft tissue level similar to the Ref 2 device (3.3 mm).

The size of cuff height is a very minor parameter and is not considered affecting substantial equivalence, the cuff height provides good gingival adaptation and the variety of the size enables to operate with a more precise treatment in order to meet each patient's gingival condition.

### 2) Fixture Diameter and Thread Depth

The subject device has major fixture diameters of 4mm, 5mm and 6mm similar to Ref. 2 device and are considered as equivalent.

The subject device has minimum thread depth slightly higher than the Ref. 1 device and are considered equivalent.

### **DISCUSSION OF DIFFERENCES**

- 1) As demonstrated in SE (Substantial Equivalent) table, **the range of Neck** rough Endosseous and Non-Threaded Section is 0.7-3.5 vs 1.0–2.0 mm for the subject device vs the Ref 2 device respectively. This non-threaded section of the implant is not significant to the primary and long-term stability. We have provided comprehensive SE table including required characteristics such as the comparison to the depth of the thread.

The subject device features a deeper thread of 0.4mm to 1.2mm (for diameters ranges from Ø 4 to Ø6) compared to AnyRidge Megagen (Ref 1) (for diameters of Ø3.5 to Ø8) which offers the thread depth of 0.35mm to 1 mm.

- 2) **The clinically relevant section of the implant with respect to the bone is the length of the threaded and non-threaded rough portion that are surface treated (L).** This portion is to be osseointegrated. According to this length, Noris' (subject device) and Ref 1 &2 lengths are equivalent, please see on SE table the parameter L (Implant Length) .

Although Noris' threaded portion (see SE table parameter Fixture Length = L- L3) is shorter compared to Ref 2, this length is indeed clinically relevant to initial stability. However, the initial stability is mostly affected by the implants features such as the **thread design** and **thread's depth** (e.g. implants dimensions) are also contributing to the stability.

- 3) **Fixture diameter of subject device** is lower than Ref 1 - This difference is related to the higher thread's depth of subject device.

The subject device has major fixture diameters of 4mm, 5mm and 6mm similar to Ref.1 adevice and are considered as equivalent (see discussion below).

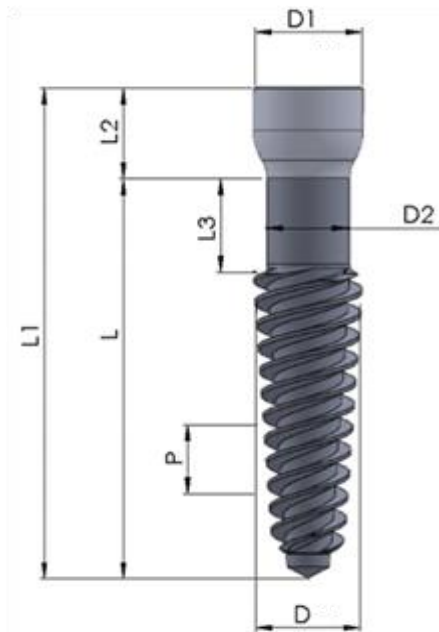
**Summary of equivalence was determined through the points in following Table 1.**



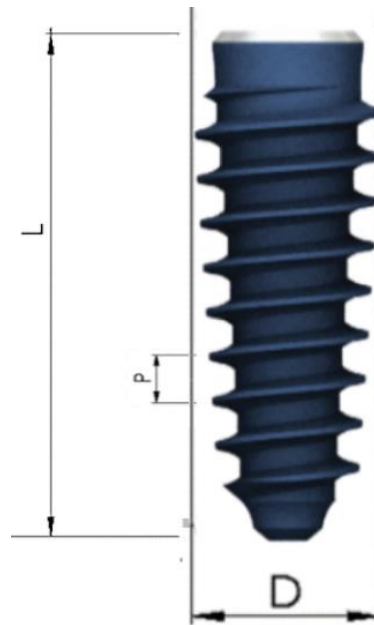
**Fig. 1** – Dimensions of the implants (Subject and references):

(A) **Cortical Noris** –Subject device (B) **AnyRidge Megagen**- Ref. 1 (C) **Straumann TLX** –Ref.2

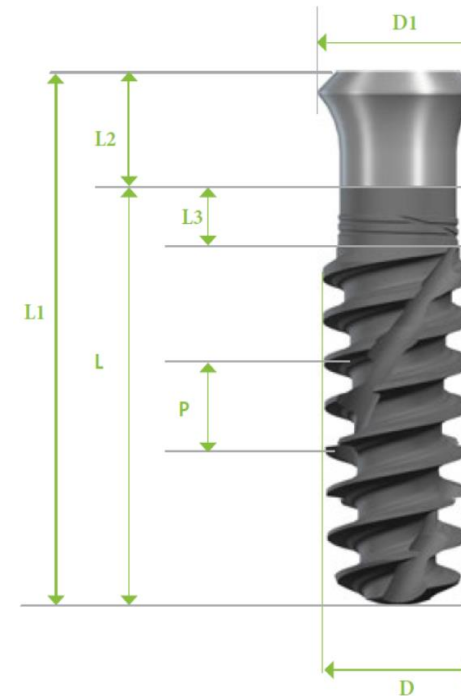
**A. Cortical Noris**







**B. AnyRidge Megagen**



**C. Straumann TLX**



**Table 1-** Summary of Equivalence

Feature	Subject Device/Present Submission	Predicate Device	Reference Device 1	Reference Device 2	Equivalent or Identical
<b>510(k) Number</b>	K210852	K140440	K140091	K200586	-
<b>Device Name</b>	Noris Medical Dental Implants System -Cortical	Noris Medical Dental Implants System - TUFF	Xpeed AnyRidge Internal Implant System	Straumann TLX Implant System- TLX S	-
<b>Sponsor/ Manufacturer</b>	Noris Medical Ltd	Noris Medical Ltd	MegaGen Implant Co., Ltd	Institut Straumann AG	-
<b>Design shape</b>					Equivalent to Ref. 1+2
<b>Indication for Use</b>	[1]	[1]	[2]	[3]	SE
<b>Product Code</b>	DZE	DZE	DZE	DZE	SE

Feature	Subject Device/Present Submission	Predicate Device	Reference Device 1	Reference Device 2	Equivalent or Identical
<b>Target Population</b>	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	SE
<b>Material</b>	Titanium alloy	Titanium alloy	CP Ti Grade 4	Titanium-13 Zirconium alloy (Roxolid®)	Identical to predicate
<b>Diameter [mm]</b> <i>Widest Diameter</i>	4.0, 5.0, 6.0	3.3, 3.75, 4.2, 5, 6	For normal ridge: 4.0, 4.4, 4.9, 5.4, 5.9  For low ridge: 6.4, 6.9, 7.4, 7.9, 8.4	3.75, 4.0, 4.5, 5.0, 5.5, 6.5	Identical to Predicate and Ref.1. The Subject device is for Normal ridge only
<b>Full Body Length [mm]- L1</b>	For Ø4.0: 11.5, 13, 16, 18, 20  For Ø5.0: 11.5, 13.0, 16.0  For Ø6.0: 11.5, 13.0, 16.0	8, 10, 11.5, 13, 16	8.5, 10, 11.5,13,15	11.3, 13.3,15.3, 17.3, 19.3	SE

Feature	Subject Device/Present Submission	Predicate Device	Reference Device 1	Reference Device 2	Equivalent or Identical
<b>Implanted Length [mm]- L</b>  <i>Length within the bone (and surface treated for osseointegration)</i>	For Ø4.0: 7.5, 9, 12, 14, 16  For Ø5.0: 7.5, 9, 12  For Ø6.0: 7.5, 9, 12	For Ø3.3, Ø3.75, Ø4.2, Ø5: 8, 10, 11.5, 13, 16  For Ø6: 8, 10, 11.5, 13	For Ø 4.0, Ø 4.4, Ø 4.9, Ø 5.4, Ø5.9: 7, 8.5, 10, 11.5, 13, 15  For Ø 6.4: 7, 8.5, 10, 11.5, 13	For Ø3.75: 6, 8, 10, 12, 14, 16, 18  For Ø4.5: 8, 10, 12, 14, 16, 18  For Ø5.5: 8, 10, 12	Equivalent to predicate and Ref. 1+2
<b>Threaded Length [mm]- L-L3</b>	For Ø4.0: 6.8, 8, 10, 11, 12.5  For Ø5.0: 6.8, 8, 10  For Ø6.0: 6.8, 8, 10	NA	For normal ridge (Ø3.5-5.5): 7.7, 9.2, 10.7, 12.2, 14.2, 17.2  For low ridge (Ø6-8): 7.9, 9.4, 10.9, 12.4, 14.4	For Ø3.75: 7, 8.3, 10.3, 12.3, 14, 16  For Ø4.5: 7, 8.3, 10.3, 12.3, 14, 16  For Ø5.5: 7, 8.3, 10.3	Equivalent to Ref. 2

Feature	Subject Device/Present Submission	Predicate Device	Reference Device 1	Reference Device 2	Equivalent or Identical
<b>Gingival (Cuff) Height - [mm]- L2</b>  <b>Basket (Noris Cortical name). Tulip (Straumann TLX name)</b>  <i>Non-treated /smooth Section</i>	4	NA	NA	3.3	Equivalent to Ref. 2
<b>Thread to Shoulder Height [mm]- L3</b>  <i>Neck- surface treated rough Endosseous and Non-Threaded Section</i>	For L7.5: 0.7 For L9: 1.0 For L12: 2.0 For L14: 3.0 For L16: 3.5	NA	NA	For L8: 1.0 For L10, L12, L14: 1.7 For L16, L18: 2.0	Equivalent to Ref. 2 For Difference discussion-see below
<b>Thread Pitch [mm]- P</b>	For Ø4.0: 2.4 For Ø5.0: 2.8  For Ø6.0: 3	NA	1	For Ø3.75: 1.7, 2.2, 2.6  For Ø4.5: 2.0, 2.5, 2.8  For Ø5.5: 2.1, 2.5 For Ø6.5: 2.5,2.8	Equivalent to Ref. 2

Feature	Subject Device/Present Submission	Predicate Device	Reference Device 1	Reference Device 2	Equivalent or Identical
<b>Implant Threads Depth [mm] at Core Diameter</b> ( 3.5mm below Bone level)	For Ø4.0: 0.4, 0.45, 0.45, 0.5, 0.5  For Ø5.0: 1.04, 0.95, 1  For Ø6.0: 1.25, 1.2, 1.2	NA	For Ø4.0: 0.35 For Ø4.4: 0.35 For Ø4.9: 0.6 For Ø5.4: 0.85 For Ø5.9: 1.1 For Ø6.4: 1	NA <i>Cannot be calculated – no data</i>	Higher thread depth for subject device in comparison to Ref.1  Difference discussion-see below
<b>Prosthetic Connection</b>	Internal Hex	Internal Hex	Internal Hex	TorcFit (with conical fitting)	Identical to predicate
<b>Type</b>	Tissue level implant	Bone level Implant	Bone level Implant	Tissue level implant	Identical to Ref 2
<b>External core body</b>	Tapered core	Tapered core	Tapered core	Tapered core	Identical to predicate
<b>Design thread profile</b>	Root Form	Root Form	Root Form	Root Form	SE
<b>Surface Treatment</b>	RBM (Resorbable Blasting Media)	S.L.A (Sand-blasted, Large grit, Acid-etched).	S.L.A (Sand-blasted, large grit, Acid-etched).	Hydrophilic SLActive®	Identical to Reference K151909

<b>Feature</b>	<b>Subject Device/Present Submission</b>	<b>Predicate Device</b>	<b>Reference Device 1</b>	<b>Reference Device 2</b>	<b>Equivalent or Identical</b>
<b>Sterilization</b>	Gamma Irradiation Sterilization	Gamma Irradiation Sterilization	Gamma Irradiation Sterilization	Gamma Irradiation Sterilization	Identical to Predicate
<b>Shelf Life</b>	5 Years	5 Years	5 Years	5 Years	Identical to Predicate
<b>Clinical procedure</b>	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period	Two stages, root-form dental implants, associated with abutment systems, which provide the clinician with the screw and cement retained restoration for multi-mount options	N/A	Identical to predicate

❖ **SE-** Substantially Equivalent

## **6. PROSTHETICS COMPONENTS – Substantial Equivalence**

The Prosthetics components connected to the subject device-Cortical implants are same as the prosthetic devices submitted with predicate device - K140440.

The connection platform is 3.75mm internal Hex for all the prosthetic components.

### **Healing Caps**

	<b>Noris Medical</b>
<b>Feature</b>	
<b>K510</b>	K140440
<b>Product Name</b>	Healing cap
<b>Intended use</b>	Used to allow the gingiva to heal around implants.
<b>Material</b>	Titanium alloy
<b>Diameter (mm)</b>	3.8,4.6,5.5,6.3
<b>Height (mm)</b>	2,3,4,5,6,7
<b>Angle</b>	0
<b>Sterility</b>	Non-sterile

### **Straight abutment**





<b>Feature</b>	<b>Noris Medical</b>
<b>Product Name</b>	Straight abutment
<b>K510</b>	K140440
<b>Intended use</b>	The straight abutment is used in the fabrication of cement-retained restorations, single crowns or bridges.
<b>Material</b>	Titanium alloy
<b>Diameter (mm)</b>	3.75, 3.8, 4.5, 5.2, 5.5, 9
<b>Height (mm)</b>	6, 8, 8.5, 9, 9.5, 10, 10.5, 11, 11.5, 12, 12.5, 15
<b>Angle</b>	0
<b>Sterility</b>	Non-sterile

### Angular Abutments

<b>Feature</b>	<b>Noris Medical</b>
<b>Product Name</b>	Angular Abutments
<b>K510</b>	K140440
<b>Intended use</b>	Angular abutments are used when a change to the axis of the implant is required. Normally used for constructing cement-retained single crowns or bridges. The abutments are available with angles of 15° and 25° degrees.
<b>Material</b>	Titanium alloy
<b>Diameter (mm)</b>	4, 4.5, 5.4
<b>Height (mm)</b>	9, 9.5, 10.5, 11, 11.5, 12.5
<b>Angle (°)</b>	15, 25
<b>Sterility</b>	Non-sterile



**Esthetic Screw Abutments**

<b>Feature</b>	<b>Noris Medical</b>
<b>K510</b>	K140440
<b>Product Name</b>	Esthetic Screw Abutments
<b>Intended use</b>	Esthetic Screw Abutment is intended for the screw retained rehabilitation process on single or multiple units.
<b>Material</b>	Titanium alloy
<b>Diameter (mm)</b>	4.7
<b>Height (mm)</b>	0.5, 1.5 ,2.5
<b>Angle (°)</b>	0
<b>Sterility</b>	Non-sterile

**Ball attachment**

<b>Feature</b>	<b>Noris Medical</b>
<b>K510</b>	K140440
<b>Product Name</b>	Ball attachment
<b>Intended use</b>	The ball attachment superstructure is intended to secure a removable prosthesis.
<b>Material</b>	Titanium alloy
<b>Height (mm)</b>	0.5,1,2,3,4,5,6
<b>Angle (°)</b>	0
<b>Sterility</b>	Non-sterile

**Flat attachment**



Noris Medical prosthetics for Cortical implant is same as predicate device Tuff implant (K140440). Same platform, same internal Hex connection.

As with the Noris Medical predicate submission (K140440), the complete set of prosthetics already registered is compatible with the subject device, and provides for a complete implantation procedure.

## 7. NON-CLINICAL TEST

### **Biocompatibility**

The Noris Medical 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.

Biocompatibility risk assessment is leveraged to the Reference predicate device K151909 – Noris Medical Ltd

**Sterilization validation** tests were conducted in compliance with ANSI/AAMI/ISO 11137-1 and ISO 11137-2 in order to ensure safety and effectiveness related to Noris Medical Dental Implants System.

Test results have demonstrated that the SAL of  $10^{-6}$  was achieved and all testing requirements were met.

Pyrogenicity information provided is based on FDA Guidance on "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile." The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on USP 161.

The outer packaging and packaging materials constituting the sterile barrier are unchanged and are identical to the packaging used for the predicate K140440 - Noris Medical Ltd.

**Transportation:** A transportation simulation followed by visual inspection were made to assure the proposed packaging modification survives transportation conditions, in accordance with ASTM 4332 and ASTM D 4169.

Accelerated aging per ASTM-F-1980 have been applied on the final packaging followed by validating package integrity tests for the sterile barrier in order to substantiate 5 years shelf life.

**Performance test:** Static and dynamic compression performance test was conducted per ISO 14801 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".

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

## 8. CLINICAL TEST

**Summary:** OUS retrospective clinical study in which 40 Noris cortical implants were placed in 19 patients, 9 Male and 10 Female, ages 49-82 (average age 69) during years 2018-2019 in Israeli private clinic. The sample population was statistically derived as n=38. For inclusion in study, all patients required extraction and immediate placement of subject implant with immediate loading. Panoramic radiographs and CT were taken pre-op, along with panoramic radiographs taken immediately after implantation and after at least 6 months follow up. Radiographs provided baseline crestal bone height data for each patient case, with crestal bone level being measured from the base of the smooth, unmachined basket portion of implant body as the subject device is a tissue level device. Specific tooth crestal bone height measurements are provided for selected teeth from each panoramic film, serving as key teeth measured at baseline, 12 months and as late as 33 months. At subsequent patient evaluations, bone loss is calculated based on the total cortical dental implant length minus the 4 mm length of the smooth surface basket.

**Acceptance Criteria:** Pass Criteria for 1 Year  $\leq 1\text{mm}$ ; for 2 Years  $< 1.2\text{mm}$ ; for 3 Years  $< 1.4\text{mm}$ , with overall accuracy  $\pm 0.25\text{mm}$ . A continuous stability of implant with no inflammation after at least 6 months was considered as a success.

Implants were placed in both anterior and posterior of both mandible and maxilla. Implant full body lengths used consisted of 11.5mm, 13mm, 16mm and 18mm. All implants were placed in extraction sockets in bone density consisting of types III- IV (low density cancellous bone) with immediate restoration and occlusal loading.

**Results:** All patients were followed at least 12 months post-loading, with 11/19 followed more than 24 months for evaluation of marginal bone loss at 12 months and 24 months. Results showed 100% survival rate of implants with average marginal bone loss of 0.6mm with a standard deviation of 0.57mm.

## 9. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The Noris Medical Cortical Implant and its predicate and reference devices share equivalent intended use, and technological features, as described hereunder:

### Intended Use

Both TUFF and Cortical Implant (Noris) devices are intended to be implanted in either jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.

### Technological Features

The subject device material uses ASTM-F136 medical Grade Titanium alloy identical to the predicate device material.

Biocompatibility risk assessment is leveraged to predicate device K151909 therefore, no new issues regarding biocompatibility were raised.

Calcium phosphate blasted(RBM) is used for **surface modification** all Noris Medical dental implants system to increase bone-implant interface, and hence facilitate ossointegration.

**RBM surface treatment** was cleared under K151909-Noris Medical Zygomatic dental implant System

The Noris Medical SEM/EDS surface analysis test results showed clean surface with morphology that conforms to RBM process

The Noris Cortical implant subject device is packed in a sterile barrier packaging and is equivalent to the validated packaging of the TUFF predicate device K140440.

The Gamma radiation **sterilization process** used for the Cortical Implant subject device as recommended in the labeling was validated for TUFF predicate device and is providing sterile implants with Sterility Assurance Level (SAL) of  $10^{-6}$ .

The validation method used was the over kill bioburden method in accordance with ISO 11137-2, "Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose".

The shelf life for the devices provided sterile is 5 years and is equivalent to predicate device TUFF implant.

Pyrogenicity information provided is based on FDA Guidance on "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile." The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on USP 161. The devices will not be marketed as non-pyrogenic

**Biological assessment** for final product has been performed according to ISO 10993-1:2009 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" and to the FDA Guidance document "Use of International Standard ISO 10993- 1'Biological evaluation of medical devices – Part 1"

**Dynamic fatigue tests** were conducted according to ISO 14801 and the FDA guidance document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" and demonstrated the fatigue limit and Maximum bending moment of Cortical Implant combined to worst case abutment connection is equivalent to the predicate device K140440.

## **10. CONCLUSION**

Noris Medical Cortical Dental Implant System and its predicate device Noris Medical TUFF implant is intended for the same use, and are implanted using equivalent surgical procedures.

The Noris Medical Cortical implant external shape design is similar to reference device 1 AnyRidge Megagen for the threads design and to reference device 2 Straumann TLX for the restoration portion and neck implant design.

The minor differences between Noris Medical Cortical Dental Implant System to the predicate and reference predicates do not raise new concerns of safety or effectiveness. The Noris Medical Cortical implant System subject device is substantially equivalent, for the relevant features, to predicate device and Reference devices.

The proposed Cortical Implant, predicate and reference devices have common characteristics in all the items in the comparison chart except absolute dimensions such as the Diameter, Length and Gingival (Cuff) Height. These differences are explained not affecting the substantial equivalence.

Fatigue test was performed on the subject device and predicate device to confirm the substantial equivalence with combination of the worst-case fixture and abutment, according to 'ISO 14801' and 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment' to figure out the mechanical property. The test result supports the substantial equivalence to the predicate device.

On the basis of the comparison charts and discussion above, it is concluded that the subject device is substantially equivalent to its predicate and reference devices.