September 13, 2019

NICO Corporation
Sean Spence
Regulatory Affairs Manager
250 East 96th Street, Suite 125
Indianapolis, Indiana 46240

Re: K191599
Trade/Device Name: NICO Myriad NOVUS
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, ERL, HBC, FST, HBI
Dated: June 14, 2019
Received: June 17, 2019

Dear Sean Spence:

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,

Matthew Krueger, M.S.E.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191599

Device Name
NICO Myriad NOVUS

Indications for Use *(Describe)*
The NICO Myriad NOVUS is a powered instrument consisting of a console, handpieces, and accessories intended to perform resection and removal of soft tissue and fluids under direct visualization with or without magnification (e.g., loupes or microscope). Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open. Applications include those when access to the surgical site is limited, such as Neurosurgical/ Spinal and ENT/Otolaryngological. Specific neurosurgical indications may include diseases such as the following:

- Primary/Secondary Brain Tumors
- Vascular Abnormalities/Malformations (e.g., hemangiomas, cavernomas, and hematoma evacuation/ICH)
- Intraventricular Tumors/Cysts

The Myriad-LX illumination accessories are intended for use with the Myriad-LX light source for delivery of light to the surgical field to enhance visualization of tissue.

The NICO Automated Preservation System accessories are intended for use with the Myriad for collection and preservation of resected tissue.

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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NICO Corporation
250 E. 96th St., Suite 125
Indianapolis, IN 46240

NICO myriadNOVUS™

21 CFR §807.92
Date Prepared: 14 June 2019

Submitter/Manufacturer	NICO Corporation 250 E. 96th Street, Suite 125 Indianapolis, IN 46240
Primary Contact:	Sean Spence, RAC Regulatory Affairs Manager Office: 317.660.7118
Trade Name	NICO Myriad NOVUS™
Common/Usual Name	Electrosurgical, cutting & coagulation & accessories
Classification	21 CFR §878.4400 (Class II)
Product Code	GEI
Secondary Product Codes:	ERL, HBC, FST, HBI
Predicate Device	K182340 – NICO Myriad

Device Description

The NICO Myriad NOVUS is a minimally invasive surgical system designed for the removal of soft tissues and fluids under direct visualization. The technology platform is based on combining a minimally invasive non-heat generating reciprocating inner cannula and a stationary outer cannula with electronically controlled variable suction. The handpiece is capable of precise tissue shaving and rapid tissue debulking.

The NICO Automated Preservation System™ is a group of accessories for collection and preservation of resected tissue, it is comprised of three parts:

- *Specimen Collector* with filter element which collects tissue;
- *Specimen Infusion* Valve (SIV) which provides the desired biological environment;
- *Specimen Preserver* which provides the desired thermal condition

For standard handpieces, the Myriad-LX™ high intensity light source, handpiece sleeve, and illumination fiber combine to deliver illumination to the surgical field to aid in visualization.

The various handpieces, components, and accessories are outlined in tables below.

NICO Corporation
250 E. 96th St., Suite 125
Indianapolis, IN 46240

Table 1: Myriad Components/Accessories

Components	
NICO Myriad NOVUS	Myriad NOVUS Console and Foot Pedal
	Myriad-LX Light Source
	Cart, Aspiration Line, Nitrogen/Instrument Air Line, Power Cord, Canister
	Myriad Handpieces (multiple versions)
	Myriad-LX Handpiece Sleeve (multiple sizes)
	Myriad-LX Illumination Fiber
Automated Preservation System Accessories	Specimen Collector with Filter Element – Clamshell or Scoop
	Replacement Filter Element – Clamshell or Scoop
	Specimen Infusion Valve (SIV) - 0.50 mm or 0.76 mm Metering Line
	Specimen Preserver
Optional / Replacement Accessories	Handpiece Bending Tool
	Various DISS/Schrader Adapters & N_2 Splitter
	Replacement Handpiece Endoscope Adapters

Table 2: Myriad Standard Handpieces

CANNULA DIAMETER	CANNULA LENGTH	DESCRIPTION
15 gauge	10 cm	1510
	13 cm	1513
13 gauge	10 cm	1310
	13 cm	1313
	13 cm	Pre-Bent 1313
11 gauge	10 cm	1110
	13 cm	1113
	13 cm	Pre-Bent 1113

Table 3: Myriad Working-Channel Handpieces

CANNULA DIAMETER	CANNULA LENGTH	DESCRIPTION
19 gauge	21.5 cm	Aesculap PaediScope®
	28 cm	Karl Storz Oi HandyPro®
	28 cm	Karl Storz Little LOTTA®
17 gauge	31.5 cm	Karl Storz Decq
15 gauge	25 cm	Aesculap MINOP® & InVent
	25 cm	Karl Storz GAAB
	26.5 cm	Karl Storz LOTTA®

Indication for Use

The NICO Myriad NOVUS is a powered instrument consisting of a console, handpieces, and accessories intended to perform resection and removal of soft tissue and fluids under direct visualization. Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open. Applications include those when access to the surgical site is limited, such as Neurosurgical/Spinal and ENT/Otolaryngological.

Specific neurosurgical indications may include diseases such as the following:

- Primary/Secondary Brain Tumors

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Indianapolis, IN 46240

- Vascular Abnormalities/Malformations (e.g., hemangiomas, cavernomas, and hematoma evacuation/ICH)
- Intraventricular Tumors/Cysts

The Myriad-LX illumination accessories are intended for use with the Myriad-LX light source for delivery of light to the surgical field to enhance visualization of tissue.

The NICO Automated Preservation System accessories are intended for use with the Myriad for collection and preservation of resected tissue.

Comparison to Predicate

The NICO Myriad NOVUS is substantially equivalent to the NICO Myriad cleared under K182340. The Subject Device and the Predicate device are both used for resection and removal of soft tissue and fluids under direct visualization. Changes to the Subject Device include the addition of illumination and a console software update. These modified attributes when evaluated individually, or collectively, do not raise new questions of safety or effectiveness.

Technological Characteristics

The following table compares the subject device and predicate device.

Table 3: Technological Characteristic Comparison

	NICO Myriad K182340	**NICO Myriad K19XXXX**
510(k) #	**K182340**	To be determined
Intended Use	Powered instrument for cutting and removal of tissue and fluids.	SAME
Indications for Use	The NICO Myriad is a powered instrument consisting of a console, handpieces, and accessories intended to perform resection and removal of soft tissue and fluids under direct visualization. Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open. Applications include those when access to the surgical site is limited, such as Neurosurgical/Spinal and ENT/Otolaryngological. Specific neurosurgical indications may include diseases such as the following: • Primary/Secondary Brain Tumors • Vascular Abnormalities/Malformations (e.g., hemangiomas, cavernomas, and hematoma evacuation) • Intraventricular Tumors/Cysts	The NICO Myriad NOVUS is a powered instrument consisting of a console, handpieces, and accessories intended to perform resection and removal of soft tissue and fluids under direct visualization with or without magnification (e.g., loupes or microscope). Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open. Applications include those when access to the surgical site is limited, such as Neurosurgical/Spinal and ENT/Otolaryngological. Specific neurosurgical indications may include diseases such as the following: -Primary/Secondary Brain Tumors -Vascular Abnormalities/Malformations (e.g., hemangiomas, cavernomas, and hematoma evacuation/ICH) -Intraventricular Tumors/Cysts The Myriad-LX illumination accessories are intended for use with the Myriad-LX light source for delivery of light to the surgical field to enhance visualization of tissue. The NICO Automated Preservation System accessories are intended for use with the Myriad for collection and preservation of resected tissue.

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250 E. 96th St., Suite 125
Indianapolis, IN 46240

	NICO Myriad K182340	NICO Myriad K19XXXX
Principles of Use	User inputs via Foot Pedal and console settings to provide control over the connected handpiece to cut and remove tissues and fluids. The high-speed reciprocating cannula with electronically controlled variable suction in a disposable handpiece is capable of precise tissue shaving and rapid tissue debulking. The system modes include 'suction-only' or 'suction-with-cutting.'	SAME
Fundamental Technology	A powered instrument consisting of a console, foot pedal, handpieces, and various accessories intended to perform resection and removal of soft tissue and fluids under direct visualization. Tissue cutting and removal via scissoring action between oscillating (reciprocating) inner cannula and stationary outer cannula. Suction draws fluids and tissue into aperture for cutting and carries cut tissue away into downstream receptacle.	SAME
Console	Brand Name – NICO Myriad Gray Anodized Aluminum Accents with Painted Blue Shell	Brand Name – NICO Myriad NOVUS Blue Anodized Aluminum Accents with Painted Gray Shell
Console Software	Ver 1.50	Ver 1.52 *(1.51 never released)* - Administrative updates to code structure - Update to handpiece motor stopping algorithm
Cart	Existing Cart	Similar – with Modifications to accommodate Myriad-LX Light Source
Light Source	None	Myriad-LX Light Source
Handpieces	See Tables 2/3 Above	SAME
Accessories	NICO Automated Preservation System Optional / Replacement Accessories	SAME SAME Myriad-LX Illumination Accessories
Packaging Configurations	Packaged per Device Type	SAME Procedure Pack/Tray Configurations
Biocompatibility	Demonstrated based on externally communicating device in direct contact with tissue/bone/dentin for a limited duration	SAME
Labeling	Console Operator's Manual Handpiece IFU	SAME Handpiece IFU – Minor Changes Illumination IFU - new APS IFU – extracted from handpiece IFU
Sterility	Gamma (handpiece and certain accessories)	SAME

The Myriad NOVUS has the same principles of use and fundamental technology as the predicate. The technological and design differences do not raise new questions of safety or effectiveness and where applicable the nonclinical testing provides adequate means to assess the effects of the subject device as compared to the predicate.

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Nonclinical Testing

The following tests were successfully repeated/completed to demonstrate that the subject device met all applicable design and performance requirements, and supports a determination of substantial equivalence:

- Biocompatibility per ISO 10993-1
- Specification Review & Dimensional Analysis
- Tensile Testing
- Illumination Characteristics
- Longevity
- Thermal Characteristics
- Product Stability
- Sterility Testing/Adoption
- Packaging Stability
- Packaging Performance
- Software Project Plan
- Software Design Architecture
- General Console Verification
- Software Unit Testing

Conclusion

The subject device and the predicate are equivalent in terms of intended use and technological considerations. Risk assessments and testing activities have demonstrated that the design differences do not raise new questions of safety or effectiveness. Therefore, the conclusion drawn from these activities is that the NICO Myriad NOVUS is as safe, as effective, and performs as well as or better than the legally marketed predicate Myriad.