September 20, 2018

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

Re: K182340
Trade/Device Name: NICO Myriad
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, ERL, HBC
Dated: August 27, 2018
Received: August 28, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*

Device Name
NICO Myriad

Indications for Use *(Describe)*

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

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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10.0 510(k) SUMMARY

NICO Myriad™
21 CFR §807.92
Date Prepared: 27 August 2018

510(k) Number: K182340

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™
Common/Usual Name	Electrosurgical, cutting & coagulation & accessories
Classification	21 CFR §878.4400 (Class II)
Product Code	GEI
Secondary Product Codes:	ERL, HBC
Predicate Device	K161307 – NICO Myriad

Device Description

The Myriad 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 disposable handpiece is capable of precise tissue shaving and rapid tissue debulking.

The various handpieces, components, and optional accessories are outlined in tables below. Of note, the system also consists of optional Tissue Preservation System (TPS) accessories. The TPS is a collection of accessories which attach to the Myriad handpiece to capture resected tissue that would otherwise be discarded in the waste canister. The TPS 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

These TPS accessories can be arranged in a multitude of ways depending on the desired setup. Refer the handpiece IFU for additional details. The following tables outline the system, components, accessories, and various handpieces sizes.

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Table 1: Myriad System Components/Accessories

Components	
Myriad	Console and Foot Pedal
	Handpieces (multiple versions)
	Console Cart, Aspiration Line, Nitrogen Line/Instrument Air Line, Power Cord, Canister (single-use)
Optional Accessories	Handpiece Bending Tool
	Various DISS/Schrader Adapters & N_2 Splitter
	Replacement Handpiece Endoscope Adapters
Tissue Preservation System (TPS)	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

Table 2: Current Myriad Handpiece Configurations

Cannula Diameter	Cannula Length	Description
19 gauge	21.5 cm	19 ga x 21.5 cm (PaediScope®)
	28 cm	19 ga x 28 cm (Oi®)
	28 cm	19 ga x 28 cm (Little LOTTA®)
17 gauge	31.5 cm	17 ga x 31.5 cm (Decq)
15 gauge	10 cm	15 ga x 10 cm (1510)
	13 cm	15 ga x 13 cm (1513)
	25 cm	15 ga x 25 cm (MINOP®)
	25 cm	15 ga x 25 cm (GAAB)
	26.5 cm	15 ga x 26.5 cm (LOTTA®)
13 gauge	10 cm	13 ga x 10 cm (1310)
	13 cm	13 ga x 13 cm (1313)
	13 cm	13 ga x 13 cm (Pre-Bent 1313)
11 gauge	10 cm	11 ga x 10 cm (1110)
	13 cm	11 ga x 13 cm (1113)
	13 cm	11 ga x 13 cm (Pre-Bent 1113)

Indication 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

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Comparison to Predicate

The NICO Myriad is substantially equivalent to the NICO Myriad cleared under K161307. The subject iteration of the 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 being assembled by a new contract manufacturer, design enhancements/process improvements, capital equipment changes, packaging changes, additional handpiece offering, and labeling updates. 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 K161307	**NICO Myriad K18XXXX**
510(k) #	**K161307**	To be determined
Intended Use/ Indications	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	SAME
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

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	NICO Myriad K161307	NICO Myriad K18XXXX
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
Contract Manufacturer	*differences from predicate identified in right column	New Contract Manufacturer
Design Enhancements / Process Changes	*differences from predicate identified in right column	- Equivalent electronic components - Console pneumatic/Teflon tape usage - Change in bonding method for inner cannula to plastic components - Adhesive changes - Manufacturing Fixtures - Laser etching - Foot pedal cable strain relief - Console overlay updates to accommodate UDI direct-part-marking requirement
Adjustments to Prints during manufacturing transfer	*differences from predicate identified in right column	- More detail on cannula prints - Several injection molded parts were re-tooled requiring print adjustments - Gasket print now has the material listed and a defined dimension for outer diameter - Luer Hub added new overall length - Assembly, Split Cable print has additional notes and details regarding the overall length - Dimensional changes to re-tooled injection molded plastic components
Packaging	*differences from predicate identified in right column	- Thicker polypropylene portion of Tyvek header bag - Dimensional changes to handpiece corrugated box, heavier corrugated material - Dimensional changes to handpiece tray
Handpieces	*differences from predicate identified in right column	Added 11 ga x 13 cm Pre-Bent handpiece
Biocompatibility / Materials	Demonstrated based on externally communicating device in direct contact with tissue/bone/dentin for a limited duration	SAME
Labeling	*differences from predicate identified in right column	- Console/foot pedal updates to accommodate UDI direct-part-marking requirement - Operator's Manual updates to align with International version and identify information on updated rear overlay - Handpiece IFU updates to list new factory pre-bent 1113 handpiece offering
Sterility of Sterile Components	Gamma (handpiece and certain accessories)	SAME

The Myriad has the same fundamental technology as the predicate device. 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.

Nonclinical Testing

The following tests were successfully repeated to demonstrate that the proposed modifications met applicable design and performance requirements, and supports a determination of substantial equivalence:

- Biocompatibility per ISO 10993-1
- Longevity Testing
- Specification Review & Dimensional Analysis
- Usability & Design Validation
- IEC 60601-1 Testing
- Sterility Testing
- Packaging Stability
- Packaging Performance
- Product Stability
- Various Process Validations

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 is as safe, as effective, and performs as well as or better than the legally marketed predicate Myriad.