DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2016

Nico Corporation
Mr. Sean Spence
Regulatory Affairs Manager
250 E. 96th Street, Suite 125
Indianapolis, Indiana 46240

Re: K161307
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: November 11, 2016
Received: November 14, 2016

Dear Mr. 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. 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,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161307

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.

4.0 510(K) SUMMARY

NICO Myriad™

21 CFR §807.92

Date Prepared: 19 December 2016

510(k) Number: __K161307__

Submitter:	NICO Corporation 250 E. 96th Street, Suite 125 Indianapolis, IN 46240
Contact Person:	Sean Spence, RAC Regulatory Affairs Manager Office: 317.660.7118
Trade Name:	NICO Myriad™
Common Name:	Electrosurgical, cutting & coagulation & accessories
Classification:	21 CFR §878.4400 (Class II) 21 CFR § 874.4250 (Class II)
Product Code:	GEI
Secondary Product Codes:	ERL, HBC
Predicate Devices:	K955168, Promex Surgical Cutter, §878.4400, GEI K972865, Promex ENT Tissue Removal System, §874.4250, ERL K002523, Advantage Drive System, §882.4360, HBC, §878.4820, GEY

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.

In addition to the system and handpiece accessories or replacement parts, this submission also covers the Tissue Preservation System (TPS). 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.

Table 1: Myriad System Components/Accessories

Components	
Myriad	Console and Foot Pedal
	Handpieces (multiple versions)
	Console Cart, Canister, Aspiration Line, Nitrogen Line, Power Cord
Optional Accessories	Handpiece Bending Tool
	Various DISS/Schrader Adapters & N_2 Splitter
	Replacement Handpiece Endocsope Adapters
Tissue Preservation System (TPS)	Specimen Collector with Filter Element
	Replacement Filter Element
	Specimen Infusion Valve (SIV)
	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)
11 gauge	10 cm	11 ga x 10 cm (1110)
	13 cm	11 ga x 13 cm (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

Comparison to Predicates

The NICO Myriad is substantially equivalent to the Promex Surgical Cutter (K955168) that is indicated for the removal of tissue during pelviscopic, laparoscopic, percutaneous and open surgical procedures whenever access to the surgical site is limited, the Promex ENT Tissue Removal System (K972865) that is indicated for the removal of soft tissue and bone in the ear, nose & throat, and the Advantage Drive System (K002523) that is indicated for removal of soft tissue and bone. All three devices have the same intended use, *i.e.*, they are powered instruments for cutting and removal of tissue and fluids. The specificity provided in the Myriad's indication statement relate to anatomical areas and procedures that are widely understood to present soft tissue or fluid conditions that require removal. The specific neurosurgical indications are supported by a considerable knowledge base of clinical literature that substantiates the inclusion of these specific uses within the previously cleared general use of the Promex Surgical Cutter (refer to Clinical Review section below).

Technologically, the differences between the NICO Myriad and its predicates are that the handpiece in the subject device is a fully disposable single piece compared to a reusable handle and single-use cannula in the predicates. In addition, the subject device has a fixed reciprocation speed, whereas the predicates' reciprocation speeds can vary. These differences do not raise new questions of safety or effectiveness because the functionality and control of the amount of cutting is maintained.

Technological Characteristics

The following table compares the subject and predicate devices, including technological characteristics.

	Subject Device NICO Myriad	**Predicate Device**		**Predicate Device** Linvatec/ConMed Advantage Drive System
		Promex Surgical Cutter	**Promex ENT Tissue Removal System**	
510(k)	TBD	K955168	K972865	K002523
Device Name	NICO Myriad	Promex Surgical Cutter	Promex ENT Tissue Removal System	Advantage Drive System
Regulation / Code	§878.4400, GEI	SAME	§874.4250, ERL	§882.4360, HBC | §878.4820, GEY
Common Name	Electrosurgical, Cutting & Coagulation & Accessories	SAME	Drill, Surgical, Ent (Electric Or Pneumatic) Including Handpiece	Motor, Drill, Electric | Motor, Surgical Instrument, Ac-Powered
Intended Use	Powered instrument for cutting and removal of tissue and fluids	SAME	SAME	SAME

	Subject Device **NICO Myriad**		**Predicate Device**		**Predicate Device** **Linvatec/ConMed Advantage Drive System**
			Promex Surgical Cutter	**Promex ENT Tissue Removal System**	
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		For the morcellation and removal of tissue during pelviscopic, laparoscopic, percutaneous and open surgical procedures whenever access to the surgical site is limited.	For the removal of soft tissue and bone in the ear, nose & throat.	The Advantage® Turbo Drive System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurosurgical, Orthopedic, Otolaryngological, Oral/Maxillofacial, Plastic/Reconstructive and Spinal surgical procedures.
Cutting Action / Control	Mechanical / User inputs via Foot Pedal and front panel settings to provide control over the connected handpiece.		SAME		SAME
Handpiece Design	1-piece handle/cannula component		2-piece, separate handle and cannula/blade		2-piece, separate handle and shaver blade components
Handpiece Types	Single type, tissue shaver		SAME		Multiple blade types, including tissue shavers, drills, burrs, and routers
Function	Tissue cutting and removal system 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		Shaver Handpieces: Tissue cutting and removal system via scissoring action between oscillating (rotational) inner cannula and stationary outer cannula. Suction draws fluids and tissue into aperture for cutting and carries cut tissue away into downstream receptacle.
Primary System Modes	1. Suction only 2. Suction with **fixed** oscillation (reciprocating)		1. SAME 2. Suction with **variable** oscillation (reciprocating)		1. SAME 2. Suction with **variable** oscillation (reciprocating)
System Principle of Operation	**Cutting Speed**	Fixed	Variable		Variable
	Aspiration	Variable	Variable		Variable

	Subject Device NICO Myriad	Predicate Device		Predicate Device Linvatec/ConMed Advantage Drive System
		Promex Surgical Cutter	Promex ENT Tissue Removal System	
Suction/ Vacuum creation	Vacuum created within console	SAME		Wall vacuum (i.e., central vacuum supply in hospital)
Use	Console/Foot Pedal = Reusable Capital Handpiece = Fully Disposable	Console/Foot Pedal = SAME Handpiece = 2-piece, reusable handle & single-use cannula		Console/Fool Pedal = SAME Handpiece = 2-piece, reusable handle & single-use blade
Materials / Biocomp.	Stainless steel Cannula/Blade portion for limited duration (≤ 24 hours). Demonstrated based on externally communicating device in direct contact with tissue/bone/dentin for a limited duration	SAME		SAME
Sterility (if applicable)	Gamma (handpiece only)	SAME (blades only)		Gamma (blades only)

Non-Clinical Testing

The following non-clinical testing was performed:

Description	Result
Console & Foot Pedal	
Console/Foot Pedal Packaging Testing	Passed
General Verification Testing including review of specifications	Passed
Console Life Cycle Testing on functionality during/following repetitive use	Passed
Console Environmental Testing on functionality under environmental extremes	Passed
Firmware Unit Plan, Design, & Verification	Passed
Handpieces	
Sterility, Packaging, and Shelf Life Testing	Passed
Biocompatibility per ISO 10993 (Cyto, Sensi, Irri, Pyro, Hemo)	Passed
Simulated Use of system and ability to cut surrogate materials/tissue while using handpieces bent to maximum allowable angle	Passed
Endoscope Compatibility on functionality with applicable commercially available endoscopes	Passed
Physical Characteristics Verification on material selection, fabrication methods, and multiple bonds/joint/weld evaluations	Passed
Life Cycle Testing on functionality during/following repetitive use	Passed
Environmental Testing on functionality under environmental extremes	Passed
Accessories	
Replacement Working Channel Adapters Packaging & Shelf Life Testing	Passed
Specimen Collector and Filter Element Verification including Sterility, Packaging & Shelf Life	Passed
Bending Tool Verification, including Sterility, Packaging, Shelf Life, and Biocompatibility per ISO 10993 (Cyto, Sensi, Irri, Pyro, Hemo)	Passed
Specimen Infusion Valve Verification including Sterility, Packaging, & Shelf Life Testing	Passed
NICO Myriad System	
Usability	Passed
IEC 60601-1 General Electrical Safety Testing	Passed
IEC 60601-1-2 EMC Testing	Passed

Clinical Review

In addition to the non-clinical testing, data on the current clinical usage of the Myriad was provided (i.e., peer reviewed journal articles and case report surveys) to support the added specificity. These citations, along with the post-market surveillance, show that intracranial tumors, vascular abnormalities or malformations, and intraventricular tumors/cysts are a known subset of the previously cleared general use to cut and remove soft tissue and fluids. This body of evidence reflects existing understanding by the medical community that the more specific use is a subset of the general use.

The types of procedures and surgeries identified in the Myriad's indication statement relate to anatomical areas that are widely understood to present soft tissue or fluid conditions that require removal. Since NICO began commercially distributing the Myriad system, the company focus has been in neurosurgery, thus most of the data are within that specialty. As part of continuous improvement and post-market surveillance, NICO obtains physician feedback on some of their cases in the form of case reports. These case reports were obtained directly on the Myriad (n = 1205) and when the Myriad is used in conjunction with the complimentary NICO BrainPath (n = 617) access device (K150378). These 1822 case reports predominantly included uses for primary/secondary brain tumors, vascular clot removal/hemorrhage (i.e., ICH), and cysts. In addition, 33 citations and 12 posters/abstracts were provided to corroborate the case report usage patterns. These citations represent over 500 clinical uses of the Myriad for primary/secondary brain tumors[1,2], vascular abnormalities/malformations[3,4] (e.g., hemangiomas, cavernomas, and hematoma evacuation), and intraventricular tumors/cysts[5], among other less common uses. The footnoted items are examples of those specific uses. For the latest bibliography contact NICO Clinical Affairs or refer to www.niconeuro.com.

In sum, these specific examples of uses for cutting and removal of soft tissue and fluids identified in the subject Myriad's indications statement are understood by the medical community to represent a subset of the surgical procedures for which a device such as the Myriad can be used.

Conclusion

Based upon a comparison of the intended use, technological characteristics, non-clinical performance testing, and clinical review, the subject NICO Myriad is substantially equivalent to the predicates. These data show that the differences do not raise different questions of safety or effectiveness and that the subject device is at least as safe and effective as the predicates.

[1] Labib M, Young RL, Rovin RA, Day JD, Eliyas JK, Bailes JE. The safety and efficacy of diffusion tensor imaging (DTI)- guided Transulcal radial tubular corridors to subcortical neoplasms: A multicenter study. Abstract presented at: 2015 Congress of Neurological Surgeons Annual Meeting; September 26-30, 2015; New Orleans, LA
[2] Kassam AB, Labib MA, Bafaquh M, et al. Part II: an evaluation of an integrated systems approach using diffusion-weighted, image-guided, Exoscopic-assisted, transulcal radial corridors. Innovative Neurosurg. 2015; 3(1-2): 25-33.
[3] Labib MA, Shah M, Kassam AB, et al. The Safety and Feasibility of Image-Guided BrainPath-Mediated Transsulcul Hematoma Evacuation: A Multicenter Study. [Published online ahead of print June 17, 2016] Neurosurgery. 2016. DOI: 10.1227/NEU.0000000000001316.
[4] Bauer AM, Rasmuseen, PS, Bain, MD. Initial Single-Center Technical Experience With the BrainPath System for Acute Intracerebral Hemorrhage Evacuation. [Published online ahead of print May 28, 2016] Operative Neurosurgery 2016. DOI: 10.1227/NEU.0000000000001258.
[5] Eliyas JK, Glynn R, Kulwin CG, et al. Minimally Invasive Transsulcal Resection of Intraventricular and Periventricular Lesions Through a Tubular Retractor System: Multicentric Experience and Results. World Neurosurg. 2016;90:556-64.