DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 7, 2017

NICO Corporation
Sean Spence
Regulatory Affairs Manager
250 E 96th St. Suite 125
Indianapolis, Indiana 46240

Re: K172433
Trade/Device Name: NICO BrainPath
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor for Neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: August 10, 2017
Received: August 11, 2017

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 (DICE) 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 (DICE) 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K172433

Device Name
NICO BrainPath

Indications for Use *(Describe)*
To provide for access and allow for visualization of the surgical field during brain and spinal surgery. Indications may include subcortical access to diseases such as the following:

- Primary/Secondary Brain Tumors
- Vascular Abnormalities/Malformations
- 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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NICO BrainPath®

21 CFR §807.92
Date Prepared: 06 September 2017

510(k) Number: K172433

Submitter/Manufacturer: 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® BrainPath®

Common/Usual Name: Self-retaining retractor for neurosurgery

Classification / Panel: 21 CFR §882.4800 / Neurology

Product Codes: GZT

Predicate Device: K150378, NICO BrainPath

Device Description

The NICO BrainPath and accessories are designed to provide minimally invasive access to neurological tissues. The design specifically supports the creation of an atraumatic surgical corridor to access the brain. These BrainPath devices are part of what is being called the BrainPath Approach™, which integrates the expanding neurosurgical armamentarium of trajectory planning and navigation, optics, corridor resection and biopsy, and tissue preservation. To date, the BrainPath technology has been used to successfully access primary and secondary brain tumors, vascular abnormalities or malformations, and intraventricular tumors and cysts.

The BrainPath consists of multiple-sized reusable and re-sterilizable obturators with coordinating single patient use disposable sheaths. The obturator and sheath are assembled in the operating room immediately prior to use. After placement, the obturator is removed leaving behind the sheath which provides a 13.5 mm or 11 mm surgical corridor. Table 1 outlines the available BrainPath configurations.

Table 1: BrainPath Configurations

Name	Sheath Inner-Diameter (mm)	Sheath Length (mm)	Obturator Tip (mm)
13.5 mm x 50 mm (ST)	13.5	50	7.5
13.5 mm x 50 mm		50	15
13.5 mm x 60 mm		60	
13.5 mm x 75 mm		75	
13.5 mm x 95 mm		95	
11 mm x 50 mm	11	50	
11 mm x 60 mm		60	
11 mm x 75 mm		75	

The BrainPath accessories include a Manipulation Tool which is used for manipulating the position of the sheath after it has been placed, Shepherd's Hooks which are for attaching to various commercially available retractor arms, a 95 mm Stylet for use with the 95 mm obturator, and a Sterilization Tray for sterilization of the reusable components (i.e., obturators, manipulation tools, and 95 mm stylet).

Table 2: NICO BrainPath Components Supplied

BrainPath Component	Sterile or Non-Sterile	Single-Use or Reusable
Sheath (all sizes)	Sterile	Single-Use
Obturators (all sizes)	Non-Sterile	Reusable
Manipulation Tool	Non-Sterile	Reusable
95mm Stylet	Non-Sterile	Reusable
Sterilization Tray	Non-Sterile	Reusable
Shepherd's Hooks (all types)	Sterile	Single-Use

Intended Use

To provide for access and allow for visualization of the surgical field during brain and spinal surgery. Indications may include subcortical access to diseases such as the following:

- Primary/Secondary brain tumors
- Vascular abnormalities/malformations
- Intraventricular tumors/cysts

Comparison to Predicate

The subject BrainPath iteration is nearly identical to the predicate NICO BrainPath (K150378). Modifications include a concave proximal sheath ring geometry to reduce optical glare, and a product line extension to include a 13.5 mm x 95 mm and 11 mm set of offerings. The 95 mm length Obturator also necessitated the creation of a new 95 mm stylet accessory. Table 3 provides additional details on how the subject and predicate devices compare.

Table 3: Comparison Table

	Predicate Device NICO BrainPath	Subject Device NICO Brain Port
Device Name	BrainPath	Identical
Intended Use	To provide for access and allow for visualization of the surgical field during brain and spinal surgery. Indications may include subcortical access to diseases such as the following: - Primary/Secondary brain tumors - Vascular abnormalities/malformations - Intraventricular tumors/cysts	Identical
Principle of Operation	Consists of an "obturator-like" component and a "sheath-like" component which are assembled, inserted, and disassembled to provide corridor access	Identical
Operation and placement	Handheld and can be assisted by third-party navigation (if desired)	Identical

	Predicate Device NICO BrainPath	Subject Device NICO Brain Port
Shipping Configuration	Obturator and sheath packaged and shipped separately and paired during surgical case	Identical
Reusable or Single Patient Use	Single Patient Use and Reusable	Identical
Method of Sterilization / SAL	Disposables: Gamma (sheath/hooks) / 10^{-6} Reusables: Autoclave/hydrogen peroxide gas plasma	Identical
Biocompatibility	Demonstrated based on externally communicating device in direct contact with tissue/bone/dentin for a limited duration	Identical
Materials of Manufacture	Obturator: Aluminum Sheath: COC	Identical
Cross Sectional analysis of Obturator/ Sheath	Obturator/Sheath combination has a circular cross section	Identical
Depth markings	Incremental depth markings on both sheath and obturator.	Identical
Sheath inner diameter (mm) options	13.5 mm	13.5 mm and 11 mm
Sheath Lengths	13.5 mm diameter: 50, 60, and 75 mm	13.5 mm dia.: 50, 60, 75, and 95 mm 11 mm dia.: 50, 60, 75 mm
General Shape of Obturator Tip	Distal end of obturator has a conical shape with a rounded tip and no opening.	Identical
Obturator Tip	For the blue, standard tip obturators, the tip extends 15 mm beyond the sheath. For the Gold-ST, shallow-tip obturator, the tip extends 7.5 mm beyond the sheath.	Identical, new offerings all have 15 mm tips
Third-Party instrumentation	Obturator component interfaces with third-party instruments.	Identical
Surface of Sheath	Inner diameter and horizontal proximal surface of the knurled ring are textured.	Identical
Proximal End of Sheath	Knurled ring and proximal portion of the sheath has holes, slots, and tabs.	Updated knurled ring with concave geometry to reduce optical glare, still includes holes, slots and tabs.
Manipulation Tool	"Manipulation Tool" is textured to prevent glare/shine from surgical lighting.	Identical
Shepherd's Hooks	Three Shepherd's Hooks available to facilitate interfacing with common third-party retractors.	Identical
95mm Stylet	None	For use with 13.5 mm x 95 mm Obturator as a point of attachment for third-party instruments

Non-Clinical Testing

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

Table 4: Non-Clinical Testing

Testing	Device(s) Supported	Result/Conclusion
Cytotoxicity – MEM Elution: 72 hour incubation	All	Non-cytotoxic
Sensitization – Maximization (2 extracts)		Non-sensitizer
Irritation – Intracutaneous Reactivity (2 extracts)		Non-irritant
Simulated Use to demonstrate the BrainPath has the ability to interface with third-party Instruments and meets design input requirements	All	Pass
Packaging & Shelf Life – shipping/distribution simulation, environmental conditions, aging, visual packaging inspection, bubble and seal strength packaging testing, and functional testing following aging, environmental and shipping simulation	All	Pass
Specification Review	All	Pass
Cleaning Validation (Reusable Devices) – Establishment of cleaning validation per miles soil test using bioburden endotoxin and protein testing	Obturator, Manipulation Tools, Stylet, and Sterilization Tray	Pass
Sterility Validation (Reusable Devices) – Steam autoclaving, IUSS, and hydrogen peroxide gas plasma	Obturators, Manipulation Tools, Stylet, and Sterilization Tray	Pass
Sterility Validation (Single-Use) – B&F testing, VDmax for SAL 10^{-6}, along with routine Endotoxin testing	BrainPath Sheath and Shepherd's Hooks	Pass
Sterilization Tray Drop Test	Obturators, Manipulation Tools, Stylet, and Sterilization Tray	Pass

Conclusion

Risk assessment, biocompatibility, non-clinical testing, design validation, and compliance with recognized standards have demonstrated that the subject NICO BrainPath modifications do not raise different questions of safety or effectiveness when compared to the predicate. Therefore, the results of these analyses provide reasonable assurance that the NICO BrainPath has a similar safety and effectiveness profile as the predicate device and supports a determination of substantial equivalence.