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

June 12, 2015

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

Re: K150378
Trade/Device Name: NICO® BrainPath® and Accessories
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor for Neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: May 13, 2015
Received: May 14, 2015

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,

Carlos L. Pena -S FDA

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150378

Device Name
NICO BrainPath and Accessories

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: 03 June 2015

510(k) Number: K150378

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® and Accessories
Common/Usual Name:	Self-retaining retractor for neurosurgery
Classification:	21 CFR §882.4800
Product Codes:	GZT
Predicate Device:	K120691, NICO Brain Port (previous name)

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 most areas of the brain. The BrainPath also facilitates the expanding neurosurgical armamentarium of trajectory planning software (e.g., Synaptive® Medical Inc. BrightMatter® Planning Software, K140337), navigation (e.g., Synaptive BrightMatter Navigation System, K142024), optics, corridor resection (e.g., NICO Myriad), and biopsy. 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 surgical corridor to the lesion or abnormality. Table 1 outlines the four currently available BrainPath configurations.

Table 1: BrainPath Configurations

General Name	Sheath Length (mm)	Obturator Tip Length (mm)
50 mm Shallow-Tip (ST-Gold)	50	8
50 mm BrainPath	50	15
60 mm BrainPath	60	15
75 mm BrainPath	75	15

The BrainPath Accessories include a "manipulation tool," which is similar to a dental probe and is used for manipulating the position of the sheath after it has been placed. The accessories also include "shepherd's hooks" for attaching to various commercially available retractors, and a sterilization tray for the reusable components (i.e., obturators and manipulation tools).

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
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 Brain Port (K120691). Following the previous clearance the Brain Port name was changed to BrainPath®. Modifications to the design include creation of the ST-Gold shallow tip 50 mm obturator that provides access to shallow abnormalities by having a 7.5 mm obturator tip instead of 15 mm. The proximal end of the sheath was modified to include slots which enable the management of surgical patties, which are commonly used during neurosurgical procedures. Additionally, tabs were added to the proximal end of the sheath to facilitate retention of Shepherd's hooks, which may be used to help position the sheath during surgery. Finally, the surface finish on the inner diameter and proximal head of the sheath was textured to reduce optical glare during surgery. Table 3 provides additional details on how the subject and predicate devices compare.

Table 3: Comparison Table

	Subject Device NICO BrainPath	Predicate Device NICO Brain Port
Device Name	BrainPath	Brain Port
Intended Use	To provide for access and allow for visualization of the surgical field during brain and spinal surgery.	Identical
Indications for Use	Indications may include subcortical access to diseases such as the following: - Primary/Secondary brain tumors - Vascular abnormalities/malformations - Intraventricular tumors/cysts	None specifically identified
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

	Subject Device NICO BrainPath	Predicate Device NICO Brain Port
Operation and placement	Handheld and can be assisted by third-party navigation (if desired)	Identical
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	Gamma for disposable component (sheath) Autoclave/hydrogen peroxide gas plasma for reusable components	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 diameter dimensions	Available sheath diameter is 13.5 mm (inner diameter) and 15.8 mm (outer diameter).	Identical
Sheath lengths	Available sheath lengths are 50 mm, 60 mm, and 75 mm.	Identical
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.	The three blue standard tip obturators are identical. The Gold-ST was not part of the original Brain Port submission.
3rd party instrumentation	Obturator component interfaces with third party instruments.	Identical
Surface of Sheath	Used Ink Y. Inner diameter and horizontal proximal surface of the knurled ring are textured.	Used Ink X. Sheath was “clear” and smooth. Surface texturing was not part of the previous submission.
Proximal End of Sheath	Knurled ring and distal portion of the sheath has holes, slots, and ears.	Knurled ring on sheath includes holes for securing. Slots and ears were not part of the original Brain Port submission.
Manipulation Tool	“Manipulation Tool” is textured to prevent glare/shine from surgical lighting.	“Manipulation Tool” was offered but was not textured on the distal portion.
Shepherd’s Hooks	Three Shepherd’s Hooks available to facilitate interfacing with common third party retractors.	Shepherd’s Hooks were not mentioned in the previous submission.

Non-Clinical Testing

The following tests were confirmed or repeated to demonstrate that the subject device modifications met applicable design and performance requirements:

Table 4: Non-Clinical Testing

Testing	Device(s)	Result/Conclusion
Cytotoxicity – MEM Elution: 72 hour incubation	BrainPath Sheath, Obturator, and Manipulation Tool	Non-cytotoxic
Sensitization – Maximization (2 extracts)	BrainPath Sheath and Obturator	Non-sensitizer
Irritation – Intracutaneous Reactivity (2 extracts)		Non-irritant
Simulated Use to demonstrate the BrainPath has the ability to interface with 3rd Party Instruments and meets design input requirements	BrainPath Sheath, Obturator, and Manipulation Tool	Pass
Packaging & Shelf Life – shipping/distribution simulation, environmental conditions, aging, visual packaging inspection, bubble and burst packaging testing, and functional testing following aging, environmental and shipping simulation	BrainPath Sheath and Obturator	Pass
Specification Review	BrainPath Sheath, Obturator, and Manipulation Tool	Pass
Cleaning Validation (Reusable Device) – Establishment of cleaning validation per miles soil test using bioburden endotoxin and protein testing	BrainPath Obturator	Pass
Sterility Validation (Reusable Device) – Steam autoclaving, IUSS, and hydrogen peroxide gas plasma	Obturators, Manipulation Tool, and Sterilization Tray	Pass
Sterility Validation (Single-Use) – B&F testing, VDmax for SAL 10^{-6}, along with routine Pyrogenicity testing	BrainPath Sheath and Shepherd's Hooks	Pass
Sterilization Tray Drop Test from 4 ft.	Obturator and Manipulation Tool	Pass
Cytotoxicity – MEM Elution: 72 hour incubation	Shepherd's Hooks	Non-cytotoxic
Specification Review	Shepherd's Hooks	Pass

Conclusion

Risk assessments, biocompatibility, non-clinical testing, design validation, and compliance with recognized standards have demonstrated that the subject NICO BrainPath does not raise different questions of safety or effectiveness when compared to the predicate. Therefore, the results of these tests 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.