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K120691

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510(k) Summary per 807.92(a)(1)

Date Prepared: January 24, 2012

Submitter's Information

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Proposed Device

Device Proprietary Name:	Brain Port
Common Name:	Self-retaining retractor for neurosurgery, Brain Retractor, Retractor
Classification name:	Self-retaining retractor for neurosurgery
Class:	Class II /21CFR 882.4800
Product Code:	*GZT, HRX*

Indications for Use

To provide for access and allow for visualization of the surgical field during brain and spinal surgery.

Description of Device

The NICO Brain Port is a family of products that consists of multiple sized reusable and re-sterilizable obturators with coordinating single patient use, disposable sheaths– see Table 1 below. The obturator and sheath are assembled in the OR immediately prior to use. These two components are held together by an interference fit. The device when used as intended is designed to provide access to neurological tissues.

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The Brain Port system also includes 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. Finally, the Brain Port includes a custom sterilization tray which houses all reusable components (obturators and manipulation tools).

Table 1: NICO Brain Port Sterile and Reusable Components

Brain Port Component	Provided 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

Product Materials

- Obturator: Anodized Aluminum
  - Obturators available in three sizes which correspond to each sheath
- Thumb Screw: 316 Stainless Steel (part of obturator)
- Pin: 316 Stainless Steel (part of obturator)
- Sheath: Cyclic Olefin Copolymer
  - Available sheath diameter is 13.5 mm (inner diameter).
  - Available sheath lengths are 50 mm, 60 mm, and 75 mm.
- Medical Grade Ink (part of sheath)
- Manipulator: 316 Stainless Steel
- Reusable Tray: 304 Stainless Steel, Silicone

Predicate Device

Vycor ViewSite™ Access System by Vycor Medical, LLC. **(K060973)**

Summary of Technical Characteristics

The Brain Port Device was compared to the predicate device in areas of components, packaging and compatibility with third party instruments, material, design, and size range. The Brain Port device is considered to be sustainably equivalent to the predicate device. Per 21 CFR Part 807.92(a)(5), the following shows where the Brain Port device is similar and different in terms of technological characteristics.

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Table 2: Brain Port and Vycor (predicate) Comparison

Feature/ Characteristic	NICO Brain Port	Vycor ViewSite Surgical Access System	Comparison
510(k) #	TBD	K060973	---
Intended Use/ Indications	To provide for access and allow for visualization of the surgical field during brain and spinal surgery.	To provide for access and allow for visualization of the surgical field during brain and spinal surgery.	Identical
Principles of Use	Device consists of an obturator component and a sheath (or "sleeve") component. These two components are assembled (the sheath is slid over the obturator) and then inserted into and through intracranial neurological tissue (brain). The obturator is then removed while the sheath is left in place, providing access or as is often referred to as a "portal" to the desired site for surgical purposes	Device consists of an obturator component and a sheath (or "sleeve") component. These two components are assembled (the sheath is slid over the obturator) and then inserted into and through intracranial neurological tissue (brain). The obturator is then removed while the sheath is left in place, providing access or as is often referred to as a "portal" to the desired site for surgical purposes	Identical
Fundamental Technology	"Sheath-like" component transparent/translucent for visualization of surrounding tissue	"Sheath-like" component transparent/translucent for visualization of surrounding tissue	Identical
Configuration / System Components.	Two components: one reusable obturator and one sterile, disposable sheath. Sterilization tray offered for onsite sterilization of reusable obturator.	Two components (obturator and sheath), both disposable and packaged sterile.	Different: NICO provides one single use sterile component (sheath) and one reusable non-sterile component (obturator). Both of the predicate components are provided sterile for single use. Sterility validation for reusable component (including tray) demonstrates safety (TPR-3551; see Appendix B).

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Feature/ Characteristic	NICO Brain Port	Vycor ViewSite Surgical Access System	Comparison
			Simulated Use Testing of reusable component demonstrates efficacy (TPR-3549; see Appendix B).
Shipping configuration	Obturator and sheath packaged and shipped separately and paired during surgical case.	Obturator and Sheath are paired and shipped together within the same packaging.	Different: Brain Port sheath is sterile single use and is stocked within the OR. Brain Port Obturator must be sterilized onsite prior to each case and is paired with sheath in OR immediately prior to case. Predicate components are paired prior to packaging by the manufacturer and are stored in the OR in this configuration. Instructions for Use (LL-5918; see Appendix E) cover safety and efficacy. Instruct user to confirm that obturator and sheath are paired accurately (i.e. 50 mm sheath used with a 50 mm obturator). Packaging Validation for reusables covered by TPR-3552, Brain Port Packaging and Shelf Life Validation.
Reusable or Single Patient Use	Single Patient Use and Reusable	Single Patient Use Only	Different: Brain Port contains reusable obturator and manipulation tool and single use sheath; the predicate components are single use only.
Method of Sterilization	Gamma for disposable component (sheath)	Gamma	Different: Both the Brain Port and predicate sheath are

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Feature/ Characteristic	NICO Brain Port	Vycor ViewSite Surgical Access System	Comparison
	Autoclave/ hydrogen peroxide gas plasma for reusable components		sterilized via gamma irradiation. However, the Brain Port Sheath is sterilized via autoclave or hydrogen peroxide gas plasma while the predicate sheath is sterilized via gamma irradiation. See TPR-3551 for evidence that the difference in sterility method for the obturator does not affect safety or efficacy.
Biocompatible	Externally Communicating Device in Direct Contact with Tissue/Bone/Dentin, Limited Duration	Externally Communicating Device in Direct Contact with Tissue/Bone/Dentin, Limited Duration	Identical
Device design	Consists of an "obturator-like" component and a "sheath-like" component which are assembled, inserted into tissue, and disassembled to provide access.	Consists of an "obturator-like" component and a "sheath-like" component which are assembled, inserted into tissue, and disassembled to provide access.	Identical
Obturator and Sheath materials	Obturator is aluminum (reusable). Sheath (disposable) is Cyclic Olefin Copolymer (COC).	Sheath and obturator are both polycarbonate (disposable).	Different: Brain Port obturator and sheath materials are aluminum and COC, respectively. Predicate obturator and sheath are both polycarbonate. Biocompatibility Testing to cover safety for this difference (TPR-3553; see Appendix B). Simulated Use Testing to cover efficacy for this difference (TPR-

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Feature/ Characteristic	NICO Brain Port	Vycor ViewSite Surgical Access System	Comparison
			3549; see Appendix B).
Cross Sectional analysis of Obturator/ Sheath	Obturator/Sheath combination has a circular cross section.	Obturator/Sheath combination has an ovular cross section.	Different: Brain Port sheath/obturator have a circular cross section while predicate has an ovular cross section. Simulated Use Testing to prove that a circular cross section safely and effectively displaces (retracts) brain tissue (TPR-3549; see Appendix B).
Depth markings	Incremental depth markings on both sheath and obturator.	No depth markings.	Different: Brain Port has incremental depth markings while predicate has no markings. Biocompatibility Testing to address safety of markings (TPR-3553; see Appendix B). No impact on efficacy. Depth markings are for reference only and do not impact functionality of device.
Sheath diameter dimensions	Available sheath diameter is *13.5 mm (inner diameter). Maximum tissue displacement as a result of diameter of sheath *15.8 mm (outer diameter). *13.5 mm dimension reflects inner diameter of sheath. Outer diameter, which is correlated with tissue displacement, is 15.8 mm. Device size is designated by inner	Range of available sheath diameters is *12 mm to *28 mm. Maximum tissue displacement as a result of diameter of sheath is approximately *28 mm. *All dimensions listed above reflect inner diameter of sheath and are slightly smaller than the outer diameter, which is most relevant for tissue displacement. Device size is	Different: Brain Port only available in one diameter (13.5 mm) while predicate is available in a range of diameters (12mm – 28mm). Safety is addressed by the fact that the diameter of largest available version of predicate sheath exceeds the largest version of the Brain Port sheath. Therefore, the

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Feature/ Characteristic	NICO Brain Port	Vycor ViewSite Surgical Access System	Comparison
	diameter because this reflects the size of the opening through which the physician has access during surgery.	designated by inner diameter because this reflects the size of the opening through which the physician has access during surgery.	predicate will displace more tissue than the Brain Port. Efficacy relative to diameter addressed by Simulated Use Testing (TPR-3549; see Appendix B).
Sheath lengths	Available sheath lengths are *5 cm, *6 cm, and *7.5 cm. *The sheath length is called out on the labeling and is most relevant to the end user from a clinical perspective. This dimension represents the length of the port through which surgery will occur. The obturator is longer than the sheath by approximately 1.0 cm.	Available sheath lengths are *3 cm, *5 cm, and *7 cm. *The sheath length is called out on the labeling and is most relevant to the end user from a clinical perspective. This dimension represents the length of the port through which surgery will occur. The obturator is longer than the sheath by approximately 0.75 cm.	Different: Brain Port available in lengths of 5 cm, 6 cm and 7.5 cm while predicate is available in lengths of 3 cm, 5 cm, and 7 cm. Additional length of proposed device does not cause new issues of safety relative to predicate. The placement of both the predicate and the proposed device is entirely dependent upon the location of diseased tissue, not the length of the devices. Efficacy relative to length addressed by Simulated Use Testing (TPR-3549; see Appendix B).
Manipulation Tool	"Manipulation Tool" offered for manipulating the position of the sheath. Reusable device that will be sterilized onsite within the tray.	No "Manipulation Tool" offered.	Different: Brain Port System includes manipulation tool while predicate does not. The Manipulation Tool is a class I device (product code GEN) which is exempt from premarket notification requirements. Although the same "manipulation tool"

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Feature/ Characteristic	NICO Brain Port	Vycor ViewSite Surgical Access System	Comparison
			can be used with the Vycor sheath, it would be difficult since the Vycor sheath does not have a ring at the top with suture holes. The tip of the manipulation tool is sized so that it will fit into these suture holes to make positioning adjustments easier. Simulated Use testing to prove that tool is effective and does not affect efficacy of Brain Port.
Handheld manual operation and placement	Yes	Yes	Identical
Proximal End of Sheath	Knurled ring on sheath includes holes for securing to surrounding tissue via sutures after insertion.	Sheath does not include knurled ring or mechanism for securing placement after insertion.	Different: Brain Port includes knurled ring with holes for easier handling and securement to surrounding tissue (if desired). Predicate does not include knurled ring or suture holes. Simulated Use Testing to prove presence of knurled ring and suture holes do not affect the ability of the Brain Port to effectively be inserted into and retract tissue. (TPR-3549; see Appendix B).
Shape of distal end of obturator	Distal end of obturator has a conical shape with a rounded tip at its end and no opening.	Distal end of obturator has a rounded shape with an opening at its end.	Different: Brain Port obturator has a distal end which is conical in shape with a rounded tip and no opening. Predicate obturator has a distal

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Feature/ Characteristic	NICO Brain Port	Vycor ViewSite Surgical Access System	Comparison
			end which is rounded in shape and has an opening. The obturators for both the predicate and the proposed device displace brain tissue during insertion. The conical shape of the proposed device enables predictable and gradual serial dilation of brain tissue during its insertion. Simulated Use Testing to cover efficacy (TPR-3549; see Appendix B).
3rd party instrumentation	Obturator component interfaces with third party instruments.	Obturator component not designed to interface with third party instruments.	Different: Brain Port obturator is compatible with 3rd party instruments while predicate is not. Obturator includes a cavity for receiving third party instruments (if desired) and set screw for securing those instruments. These design aspects (cavity and set screw) do not affect the ability of the end user to safely achieve the indications for use. Simulated Use Testing to cover efficacy (TPR-3549; see Appendix B).

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Summary of Non-Clinical Testing/Statement of Equivalence

Multiple tests concerning product functionality, biocompatibility, packaging and sterilization have been performed to ensure that the Brain Port device is as safe and as effective as the predicate device. Specific testing included radiation sterilization validation on sterile components supplied, a cleaning method and sterilization validation of re-usable components supplied, packaging drop testing, simulated shipping, aging and environmental stress testing, In Vitro Cytotoxicity testing, Irritation and Delayed-Type Hypersensitivity biocompatibility testing, general functional, mechanical, dimensional and performance testing against pre-determined specifications and finally simulated use testing consisting of inserting the Brain Port into a medium representative of brain tissue.

The Brain Port system is very similar to the predicate device as both are considered "self-retaining retractors for neurosurgery" with identical indications for use. The Brain Port has very similar technological characteristics as both have the same general shape, size and identical principles of use. Both devices consist of an obturator type component that is paired with a sheath or sleeve and then inserted into the neurological tissue. The obturator component is then removed leaving the sheath in place which provides access to targeted tissues for surgery. Also, both are handheld manually placed devices and both have a means of securing the sheath and obturator so that they remain assembled during insertion. The minor technological differences such as shape, size, and compatibility with third party instruments have been evaluated through multiple verification and validation activities as well as critical analyses. Results of these evaluations demonstrate that these differences do not affect the ability of the Brain Port to achieve the indications for use. Concerning sterilization, the sheaths for both the Brain Port and the predicate are gamma-irradiated single use devices. Finally, both have identical patient contact per ISO 10993-1.

Conclusion

In conclusion, the data and information provided in this submission demonstrate that the Brain Port device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NICO Corporation
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JUN - 5 2012

Re: K120691
Trade/Device Name: Brain Port
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-retaining Retractor for Neurosurgery
Regulatory Class: Class II
Product Code: GZT, HRX
Dated: March 4, 2012
Received: March 7, 2012

Dear Mr. Devine:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Jessia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120691

Device Name: Brain Port

Indications For Use: To provide for access and allow for visualization of the surgical field during brain and spinal surgery.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Quynh Hoang

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120691