



Food and Drug Administration
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December 4, 2015

Navilyst Medical, Inc.
Robin Fuller
Sr. Manager, Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K153228
Trade/Device Name: NMI Port and NMI Port II
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: November 4, 2015
Received: November 6, 2015

Dear Robin Fuller:

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,



Tina Kiang -S

for Erin I. Keith, M.S.

Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and Dental
Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153228

Device Name
NMI Port and NMI Port II

Indications for Use (Describe)

The NMI Port and NMI Port II with and without PASV Valve Technology are indicated for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products. The device is also indicated for blood specimen withdrawal. When used with a power injectable needle, the NMI Port and NMI Port II are indicated for power injection of contrast media. The maximum recommended infusion rate is 5 ml/sec with a 19G or 20G non-coring power injectable needle or 2 ml/sec with a 22G non-coring power injectable needle.

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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510(k) Summary for the NMI Port and NMI Port II

K153228

Date prepared: 19-November-2015

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Robin Fuller
Sr. Manager, Regulatory Affairs
508-658-7986

C. Device Name

Trade Name:	NMI Port and NMI Port II
Common/Usual name:	Implanted port catheter
Classification Name:	Implanted port catheter, subcutaneous, implanted, intravascular infusion port and catheter

21CFR§880.5965, Class II

Classification Panel:	General Hospital
ProCode:	LJT

D. Predicate Device(s)

Trade Name:	NMI Port and NMI Port II
Common/Usual name:	Implanted port catheter
Classification Name:	Implanted port catheter, subcutaneous, implanted, intravascular infusion port and catheter

21CFR§880.5965, Class II

Classification Panel:	General Hospital
ProCode:	LJT
Predicate 510(k)s:	K122767, K131694

E. Device Description

The NMI Port and NMI Port II with and without PASV Valve Technology are a subcutaneous implantable venous access device with one reservoir and is designed for optional power injection of contrast media, CECT. The ports are designed to be accessed using a non-coring Huber needle introduced through the skin into the self-sealing silicone septum covering the reservoir.

The NMI Port and NMI Port II are available in plastic or titanium single lumen and valved or non-valved configurations. The ports are available with either silicone filled or non-filled suture fixation holes. Ports with non-filled suture fixation holes are generally utilized based on clinical need to anchor the port to the subcutaneous tissue; whereas ports with filled suture holes, designed to prevent tissue in-growth to the suture holes, are generally utilized when not anchoring the port to the subcutaneous tissue. If needed, filled suture holes are accessed through the silicone. All port configurations have a radiopaque identifier (CT mark) to identify the port as power injectable. The radiopaque catheter has graduated marks at 1 centimeter intervals and can be cut to the desired length by the clinician. Ports are provided with a variety of procedural accessories.

The NMI Port II catheter shaft incorporates Endexo polymer for improved resistance to thrombus accumulation and/or formation on the catheter.

F. Indication for Use

The NMI Port and NMI Port II with and without PASV Valve Technology are indicated for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products. The device is also indicated for blood specimen withdrawal.

When used with a power injectable needle, the NMI Port and NMI Port II are indicated for power injection of contrast media. The maximum recommended infusion rate is 5 ml/sec with a 19G or 20G non-coring power injectable needle or 2 ml/sec with a 22G non-coring power injectable needle.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed NMI Port and NMI Port II devices have identical materials, design and components and technological characteristics as predicate devices with the only difference being that the plastic port body ultrasonic welding process will be brought in-house to Navilyst Medical's manufacturing facility from the current outside contract manufacturer. Both the NMI Port and NMI Port II and predicate ports are, in brief, intended for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products; available in single lumen configurations; with and without PASV Valve Technology (Pressure Activated Safety Valve); plastic or titanium port body available with either a 6F or 8F outside diameter catheter; rated for maximum power injector settings up to 300 psi with maximum power injection flow rate up to 5 ml/second based on model; and available kitted with a variety of procedural accessories.

H. Performance Data

A risk analysis and necessary verification and validation activities to demonstrate that the design outputs of the modified device met the design input requirements were completed. The performance evaluation of the NMI Port and NMI Port II included testing conducted in accordance with the following FDA guidance documents and international standards:

- FDA's "Guidance on 510(k) Submissions for Implanted Infusion Ports dated October 1990.
- EN ISO 10555-1:2013, Sterile, Single Use Intravascular Catheters – Part 1: General Requirements
- EN ISO 10555-3:2013, Sterile, Single Use Intravascular Catheters – Part 3: Central Venous Catheters

The proposed NMI Port and NMI Port II successfully passed relevant testing per the above Guidance, standards, and pre-established acceptance criteria, including:

Test	Acceptance Criteria	Samples Tested	Results of Verification
Power Injection and Burst	<p>Port assembly must withstand 15 power injection cycles without any failures (leaking, fracturing and bursting) with an 11.8cp fluid at 300 psi maximum pressure setting and a 5 mL/sec flow rate setting for a 19 or 20 ga infusion set, and a 2 mL/sec flow rate setting for a 22 g infusion set.</p> <p>The port must then have a static burst strength of 50 psi minimum. Record burst strength.</p>	Three lots of 15 each (45 total).	<p>All samples tested met the acceptance criteria.</p> <p>Average static burst pressures were 138.7, 148.8 and 149.2 psi.</p>
Aspiration Strength – Open Ended	<p>Port must be able to be aspirated (no occlusions or wall collapses preventing aspiration) using a 10 mL syringe on an open ended catheter without leaking or bursting post 4 hour conditioning at 37°C +/- 2°C. Record as PASS/FAIL</p>	Three lots of 75 each (225 total).	All samples tested met the acceptance criteria.
Aspiration Strength – Closed Ended	<p>No leaks during aspiration with a 10 mL syringe for 15 seconds (leak = ingress of air bubbles to the syringe) post 4 hour conditioning at 37°C +/- 2°C without leaking or bursting on an occluded catheter. Record as PASS/FAIL</p>	Three lots of 75 each (225 total).	All samples tested met the acceptance criteria.
CT Ink Durability	<p>CT printing shall not flake or chip off. Additional requirements soaking port in saline at body temperature for 24 hours and perform and alcohol rub. Record as PASS/FAIL</p>	Three lots of 75 each (225 total).	All samples tested met the acceptance criteria

Port body height	1.29 +/- 0.21 cm	Three lots of 75 each (225 total).	All samples tested met the acceptance criteria
Port Body Break Strength	Must not break at less than 636 lb force. Record as PASS/FAIL	Three lots of 75 each (225 total).	All samples tested met the acceptance criteria

I. Conclusion

Based on successful results of testing and on responses to questions posed in FDA's 510(k) Decision Making Tree, the proposed device is determined to be substantially equivalent to the predicate devices.