



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

September 24, 2015

Navilyst Medical, Inc.
Michael P. Hanley
Specialist 1, Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K152069
Trade/Device Name: Exodus Array Multipurpose Drainage Catheter, Exodus Nuance
Nephrostomy Drainage Catheter, Exodus Believe Biliary Drainage
Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE, LJE, GBO
Dated: July 23, 2015
Received: July 29, 2015

Dear Michael P. Hanley,

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,


Jeffrey W. Cooper -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152069

Device Name

Exodus Array Multipurpose Drainage Catheters

Exodus Nuance Nephrostomy Drainage Catheters

Exodus Believe Biliary Drainage Catheters

Indications for Use (Describe)

Exodus Array Multipurpose Drainage Catheters are intended for percutaneous drainage of fluid or air in the chest, abdomen and pelvis, e.g., abscesses, cysts, pneumothoraces, and other general purpose drainage applications.

Exodus Nuance Nephrostomy Drainage Catheters are intended for percutaneous drainage of fluid collections in the urinary system.

Exodus Believe Biliary Drainage Catheters are intended for percutaneous drainage of the biliary tree.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – Exodus Drainage Catheters

A. Sponsor

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

B. Contact

Michael P. Hanley
Specialist I, Global Regulatory Affairs
508-658-7983

OR Wanda Carpinella
Director, Global Regulatory Affairs
508-658-7929

C. Device Name

Trade Name:

Exodus Array Multipurpose Drainage Catheter
Exodus Nuance Nephrostomy Drainage Catheter
Exodus Believe Biliary Drainage Catheter

Common/Usual Name:

Biliary, Nephrostomy, Multipurpose Percutaneous
Drainage Catheters

Classification Name:

- FGE – Catheter, Biliary, Diagnostic
21 CFR §876.5010, Class II
- LJE – Catheter, Nephrostomy Pre-
Amendment, unclassified
- GBO – Catheter, Nephrostomy, General &
Plastic Surgery 21 CFR§878.4200, Class I

Classification Panel:

Gastroenterology – Urology

Pro Code:

FGE, LJE, GBO

D. Predicate Device(s)

Predicate 510(k)

K093392

Trade Name:

Exodus Multipurpose Drainage Catheter
Exodus Nephrostomy Drainage Catheter
Exodus Biliary Drainage Catheter

Common/Usual Name:

Percutaneous Drainage Catheter

Classification Name:

- FGE – Catheter, Biliary, Diagnostic
21 CFR §876.5010, Class II
- LJE – Catheter, Nephrostomy Pre-
Amendment, unclassified
- GBO – Catheter, Nephrostomy, General &
Plastic Surgery 21 CFR§878.4200, Class I
- GBX – Catheter, Nephrostomy, General &
Plastic Surgery 21 CFR§878.4200, Class I

Classification Panel:

Gastroenterology – Urology

Pro Code:

FGE, LJE, GBO

Reference 510 (k)s

K103353, K141335, K951475, K053245

E. Device Description

The Exodus Drainage Catheter consists of a radiopaque polyurethane catheter. The distal end of the catheter is configured as a locking pigtail and is coated with GLYCE hydrophilic coating. Catheter markings are provided in centimeters on the shaft to indicate the distance from the distal tip. The Exodus Array Multipurpose Drainage Catheter (when applicable) and the Exodus Believe Biliary Catheter include a polymer marker to assist with catheter placement.

The proposed Exodus Drainage Catheters will include the following accessories: a metal cannula and a plastic cannula (all product offerings) and a 0.038” trocar needle (in multipurpose offerings only).

F. Intended Use/Indications for Use

The proposed Exodus Drainage Catheter has the following Indications for Use:

- *Exodus Array Multipurpose Drainage Catheters are intended for percutaneous drainage of fluid or air in the chest, abdomen and pelvis, e.g., abscesses, cysts, pneumothoraces, and other general purpose drainage applications*
- *Exodus Nuance Nephrostomy Drainage Catheters are intended for percutaneous drainage of fluid collections in the urinary system.*
- *Exodus Believe Biliary Drainage Catheters are intended for percutaneous drainage of the biliary tree.*

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

The proposed Exodus Drainage Catheter is substantially equivalent to the Navilyst Medical Percutaneous Drainage Catheter. When compared to the predicate, the proposed Exodus Drainage Catheters have similar materials, design, components, fundamental technology, and operating principles and the same indications for use. The modifications from the predicate device include: new catheter material and polymer marker band; addition 6F sizes; and 15cm as shortest catheter length. These similarities and differences are illustrated in the following table.

Comparison of Proposed Exodus Drainage Catheters And Predicate Percutaneous Drainage Catheter		
Characteristic	Proposed Exodus Drainage Catheters	Predicate Drainage Catheter (K093392)
Types of Catheters	Multipurpose Drainage Catheter Nephrostomy Drainage Catheter Biliary Drainage Catheter	Multipurpose Drainage Catheter Nephrostomy Drainage Catheter Biliary Drainage Catheter
Shaft Materials	Blended: Carbothane 55D (70%) Carbothane 95A (30%)	Co-extruded: Carbothane 55D (inner layer) Carbothane 85A (outer layer)
Shaft Depth Markers	Yes	Yes
Proximal Hub Assembly	SureTwist Hub locking Mechanism	SureTwist Hub locking Mechanism
Distal Hydrophilic Coating	Yes	Yes
Distal Configuration	Locking Pigtail	Non-Locking Locking Pigtail
Sizes	6, 8, 10, 12 & 14 French	8, 10, 12, & 14 French
Radiopaque Marker	Yes:	Yes

Comparison of Proposed Exodus Drainage Catheters And Predicate Percutaneous Drainage Catheter		
Characteristic	Proposed Exodus Drainage Catheters	Predicate Drainage Catheter (K093392)
	Polymer Marker band on select Multipurpose Catheters and all Biliary Drainage Catheters	Platinum / Iridium RO marker on all Biliary Drainage only
Useable Length	15 cm 25 cm 35 cm	20 cm 25 cm 35 cm
Included Insertion Accessories	Plastic Stiffening Cannula, Metal Stiffening Cannula Trocar	Plastic Stiffening Cannula, Metal Stiffening Cannula Trocar
Packaging	Tyvek/Mylar (PET/LDPE) Pouch	Tyvek/Mylar (PET/LDPE) Pouch
Sterilization Method	Ethylene oxide	Ethylene oxide

H. Performance Data

The performance evaluation of the proposed Exodus Drainage Catheter included testing conducted in accordance to the following FDA Guidance Documents, and international standards: Results of this testing demonstrate safety and effectiveness of the proposed device and substantial equivalence. Results of biocompatibility testing performed in accordance with ISO 10993-1 demonstrate the proposed device is acceptable for its intended use.

- Tensile Testing
- Catheter Surface
- RO Marker Band Scrape Test
- Radiopacity Testing
- Flow Rate Testing
- Fluid Leak Testing
- Aspiration Strength
- Catheter Column Strength
- Coating Lubricity
- Pigtail Diameter
- Suture Force to Pigtail
- Catheter Compatibility
- Biocompatibility Testing per ISO 10993-1

I. Conclusion

Based upon successful results of testing and responses to questions posed within FDA’s 510(k) Decision-Making Tree, the proposed device is determined to be substantially equivalent.