510(k) Summary

JUL 6 2012

APPLICANT NAME:	Navis Medical, Inc.
APPLICANT ADDRESS:	10000 Cedar Road Cleveland, OH 44106
CONTACT PERSON:	Richard G. Ganz Phone: (216) 264-6031 Fax: (216) 445-6514
DATE OF SUMMARY:	September 2, 2011
PROPRIETARY NAME OF DEVICE:	Navis Torquer
COMMON NAME:	Guide wire torque device
PROPOSED CLASSIFICATION:	21 CFR 870.1330 Classification Name: wire, guide, catheter Product Code: DQX
PANEL:	Cardiology Devices Panel (70)
PREDICATES:	Torque Device for Guide Wire (K910969) Guide Wire Torque Device (K072552)

INTENDED USE:

The Navis Torquer is intended to facilitate guide wire manipulation during interventional procedures.

DEVICE DESCRIPTION:

The Navis Torquer is a guide wire accessory intended to assist with the manipulation and placement of guide wires during interventional procedures. It accommodates guide wires with diameters from 0.010 to 0.038 inches and is composed of the following two components: 1) a polycarbonate cylindrical body and collet; and 2) an acetal rotatable cap.

The side-entry design of the device allows single-handed operation. To mount the device on a guide wire, the cylinder body is rotated into the cap until a tactile 'click' is felt and the longitudinal slots in both parts are aligned, the device is then mounted on the guide wire. Holding the guide wire stationary, the device is rotated onto the guide wire until the guide wire is aligned within the center of the device. The device is positioned optimally on the guide wire and then secured by

rotation of the cap or cylinder body. As the cap is rotated on the body, the collet grips the guide wire.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Navis Torquer device is loaded onto a guide wire, positioned along the guide wire at a desired location and tightened to grasp the guide wire for improved manipulation. The Navis Torquer uses the same collet-based gripping method as one of the predicate torque devices described above whereby the cap is screwed upon the cylindrical body (collet) to clamp the collet firmly against the guide wire. It is then unscrewed to release the collet's grip on the guide wire. The primary difference between the Navis Torquer and the included predicate devices is the method by which it is loaded onto the guide wire. The intended use and effect of the Navis Torquer is exactly the same as the predicate devices.

SUMMARY OF PERFORMANCE TESTING:

The Navis Torquer utilizes polymers and possesses similar working dimensions as compared to the listed predicate devices. Bench top tests have been performed to demonstrate equivalent grip and torque characteristics of the Navis Torque device compared to the predicate devices. The Navis Torquer has been evaluated and passed biocompatibility testing for cytotoxicity.

CONCLUSION:

The use of similar component materials, a similar indication for use statement and acceptable performance and biocompatibility data provides sufficient information to demonstrate that the Navis Torquer is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Navis Medical, Inc.
C/O Mr. Matthew Huddleston, Regulatory Consultant
Biomedical Device Solutions, LLC
5705 Whispering Trail
Galena, OH 43021

JUL 6 2012

Re: K112674
Trade/Device Name: Navis Torquer
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 15, 2012
Received: June 18, 2012

Dear Mr. Huddleston:

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112674

Device Name: Navis Torquer

Indications for Use:

The Navis Torquer is intended to facilitate guide wire manipulation during interventional procedures.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112674