SECTION 5 - 510(k) SUMMARY

JAN 18 2011

510(k) Number: K102979

Submitted by:	NexGen Medical Systems, Inc. 10471 Double R Blvd, Suite A Reno, NV 89521 US
Contact Person:	John Kucharczyk, CEO 775.851.7337 (o) 775.849.4162 (f)
Date Prepared:	January 3, 2011
Name of the Device:	NexGen Peripheral Guide Catheter
Proprietary Name:	Undetermined at this time
Common Name:	Percutaneous Catheter
Classification:	Catheter, Percutaneous (870.1250) Catheter, Intravascular, Diagnostic (870.1200

SUMMARY STATEMENT:

Predicate Device: The NexGen Peripheral Guide Catheter is substantially equivalent to the Cordis Vista Brite Tip Guiding Catheter (K972978) and the Terumo Radiofocus Glidecath (K090040).

Device Description:
The Peripheral Guide Catheter is a family of single use, catheters that are intended to facilitate introduction of interventional/diagnostic devices.

The NexGen Peripheral Guide Catheter features a proximal hub for attaching to ancillary devices such as Rotating Hemostasis Valves and Syringes and a distal, atraumatic tip that is radiopaque.

The catheter has a single lumen that can be used to facilitate introduction of interventional /diagnostic devices and injection of physician specified fluids.

The Guide Catheter comes in two profiles, 4F and 8F and multiple lengths. The 4F profile has a 65cm and 150cm working length and the 8F profile has a 20cm and 90cm working length.

Proximally located on the catheter shaft is a female luer connection for the attachment to a Hemostasis Valve Y Connector, which provides a means of introducing contrast media or other fluids. The Hemostasis Valve Y Connector is separate or a prepackaged component.

Intended Use: The NexGen Peripheral Guide Catheter is intended for use in the peripheral vasculature for the intravascular introduction of interventional/diagnostic devices and the injection of physician specified fluids. This device is not intended for use in the coronary or cerebral vasculature.

Summary of Non-Clinical Testing

Performance Testing:

The following bench testing was conducted to verify the device met design specifications and its intended use:

- Tensile Test
- Catheter Torque Test
- Catheter Burst Pressure Test
- Catheter leak Test
- Catheter Kink Diameter Test
- Catheter Pushability – Trackability Test
- Catheter Flow Rate Test

Biocompatibility:
All appropriate biocompatibility tests for the guide catheters were successfully completed.

Summary of Substantial Equivalence:
The NexGen Peripheral Guide Catheters are similar in design, construction, indication for use and performance characteristics to other commercially available guide catheters. Mechanical, safety and biocompatibility tests were performed to verify the functional safety, structural integrity and material safety. All testing demonstrated that the NexGen Guide Catheter is comparable to the predicate devices and introduces no new safety and effectiveness issues when used as indicated.

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

NexGen Medical Systems, Inc.
c/o Mr. Craig Pagan
1050 W. NASA Blvd Suite 136
Melbourne, FL 32901

JAN 18 2011

Re: K102979
Trade/Device Name: NexGen Peripheral Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: January 3, 2011
Received: January 5, 2011

Dear Mr. Pagan:

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.

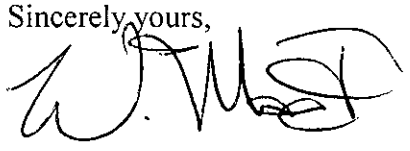
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 STATEMENT

510(k) Number: K102979

Device Name: NexGen Peripheral Guide Catheter

INDICATIONS:

Intended Use: The NexGen Peripheral Guide Catheter is intended for use in the peripheral vasculature for the intravascular introduction of interventional/diagnostic devices and the injection of physician specified fluids. This device is not intended for use in the coronary or cerebral vasculature.

CONTRAINDICATIONS:

No known contraindications.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

Page 1 of 1

510(k) Number K102979