DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 11, 2016

Mr. Greg Last
Quality Systems and Regulatory Affairs Manager
Tangent Medical Technologies, Incorporated
8170 Jackson Road, Suite A
Ann Arbor, Michigan 48103

Re: K160374
Trade/Device Name: NovaCath™ Secure IV Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: February 8, 2016
Received: February 10, 2016

Dear Mr. Last:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160374

Device Name
NovaCath™ Secure IV Catheter System

Indications for Use *(Describe)*

The NovaCath™ Secure IV Catheter System is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The needle-shielding feature aids in the prevention of needlestick injuries. Upon catheter insertion, blood is contained within the device to aid in the prevention of blood exposure. The NovaCath™ device may be utilized in any patient population with consideration given to vascular anatomy and appropriateness of procedure. The 18, 20, and 22 gauge NovaCath™ devices are suitable for use with power injectors for a maximum of 300psi.

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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Special 510(k): Device Modification
510(k) Summary
Tangent Medical Technologies, Inc.
NovaCath Secure IV Catheter System

Submission Date:	February 8, 2016
Submission Owner Information:	Tangent Medical Technologies, Inc. 8170 Jackson Rd. STE A Ann Arbor, MI 48103
Contact Information:	Greg Last Quality Systems and Regulatory Affairs Manager Greg@tangentmedical.com Tel: 734-527-4051 Fax: 734-253-2043
Device Name:	NovaCath™ Secure IV Catheter System
Proprietary Name:	NovaCath™ Secure IV Catheter System
Common Name:	Intravascular Catheter (short-term, less than 30 days, therapeutic)
Classification Name:	Intravascular Catheter
Classification Code:	FOZ
Regulation Number:	21 CFR §880.5200
Predicate Device:	NovaCath™ Secure IV Catheter System (K120839)
Device Description:	The NovaCath™ Secure IV Catheter System is a short-term, therapeutic, IV catheter. The NovaCath™ currently has four commercially available models. This special 510(k) adds two additional models of different catheter lengths to the existing gauge size portfolio. Two (2) additional models:

Gauge	20G	24G
Catheter Length	1.25”	0.56”

Are being added to the existing four (4) models cleared in K120839:

Gauge	18G	20G	22G	24G
Catheter Length	1.25"	1.00"	1.00"	0.75"

The NovaCath™ Secure IV Catheter System is comprised of an over-the-needle, radiopaque intravascular catheter, integrated extension tubing with a secondary stabilization hub, a female luer lock and clamp, and a passive safety needle shielding mechanism. The design of the NovaCath™ Secure IV Catheter System is considered a closed system since it protects users from blood exposure during the catheter insertion procedure. Blood is contained within the device after needle withdrawl by a self-sealing septum and luer lock, which is provided with a one-time use vent plug. The clamp on the extension tubing is provided to eliminate blood exposure when the vent plug is replaced with an infusion set connection or other end cap.

Intended Use:

The intended use of the device is identical to the predicate device.

The NovaCath™ Secure IV Catheter System is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The needle-shielding feature aids in the prevention of needlestick injuries. Upon catheter insertion, blood is contained within the device to aid in the prevention of blood exposure. The NovaCath™ device may be utilized in any patient population with consideration given to vascular anatomy and appropriateness of procedure. The 18, 20, and 22 gauge NovaCath™ devices are suitable for use with power injectors for a maximum of 300psi.

Comparison of Technological Characteristics:

The intended use of the device and the technological characteristics of the device are unchanged from the predicate device. The two models being added to the NovaCath™ product line per this special 510(k) use the same technology and materials as the four commercially available models. The differences are in the needle length, catheter length, and housing sizes.

The table below provides a comparison summary of the technological characteristics between the subject and predicate device.

Substantial Equivalence Comparison		
Comparison Criteria	Subject Device (NovaCath 201250 & 240560)	Predicate Device (NovaCath K120839)
Same Intended Use	Yes	Yes
Prescription Device (Rx Only)	Yes	Yes
Biocompatible Polyurethane Catheter	Yes	Yes
Biocompatible Materials of Fabrication	Yes	Yes
Closed System	Yes	Yes
Built-In Extension from Main Assembly	Yes	Yes
Flashback Visualization	Yes	Yes
Sharps Injury Prevention Feature	Yes, Passive Integrated	Yes, Passive Integrated
Mechanical	Yes, Manual Needle Retraction	Yes, Manual Needle Retraction
Intended Anatomical Location	Yes, Peripheral Vasculature	Yes, Peripheral Vasculature
Distal End Configuration	Yes, Meets ISO 10555-5	Yes, Meets ISO 10555-5
Proximal End Configuration	Yes, Female Luer Access Port	Yes, Femal Luer Access Port
Flow Rate (ml/min)	Yes, 20G: 40 ml/min Yes, 24G: 14 ml/min	Yes, 20G: 46 ml/min Yes, 24G: 14 ml/min
Catheter Stabilization	Yes, Primary and Secondary	Yes, Primary and Secondary
EO Sterilization Method	Yes	Yes
Packaged Sterile, Single Use	Yes	Yes
Non-Pyrogenic	Yes	Yes
Made without Latex Rubber	Yes	Yes
Made without DEHP	Yes	Yes
For Use with Power Injections up to 300 psi	Yes, 20G; 24G Contraindicated	Yes, 18G, 20G, 22G; 24G Contraindicated

Summary of Device Evaluation:

The device was developed and tested in accordance with released company procedures on design control (per 21 CFR 820.30) and risk analysis (per ISO 14971:2009). A declaration of conformity to design controls is located within the 510(k).

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA) per released procedures. The design verification tests completed are as follows:

Modification	**Test Performed**	**Consensus Standard**
20Gx1.25" Catheter	Power Injection Test for Flow Rate and Device Pressure	ISO 10555-1:2013
20Gx1.25" Catheter	Flow Rate Test	ISO 10555-1:2013
24G x0.56" Catheter	Flow Rate Test	ISO 10555-1:2013
24G x0.56" Catheter Modified Housing ("Slider") Component	Test Access to the Sharp in Safe Mode	ISO 23908:2011

Conclusions: The NovaCath™ Secure IV Catheter System as described in this Special 510(k) has been found to perform in the substantial equivalent manner as the predicate device.