K120839

JUL 20 2012

14. 510(k) SUMMARY

TANGENT MEDICAL TECHNOLOGIES, INC.
NOVACATH™ SECURE IV CATHETER SYSTEM

July 11, 2012

The following summary is provided pursuant to Section 513 (I) (3) (A) of the Federal Food Drug and Cosmetic Act:

Submitter Information:	Tangent Medical Technologies, Inc. 8170 Jackson Road, STE A Ann Arbor, MI 48103
Contact Information:	Kay Fuller, RAC VP, Regulatory and Clinical Affairs kay @tangentmedical .com 1+734-527-4060 / 1+734-846-7852
Device Name:	NovaCath™ Secure IV Catheter System
Proprietary Name:	NovaCath™Secure IV Catheter System
Common Name:	Intravascular Catheter (short-term)
Classification Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
Classification Code:	FOZ
Regulation Number:	21 CFR § 880.5200
Predicate Device Equivalence:	The Tangent NovaCath™ Secure IV Catheter System is substantially equivalent to the BD Nexiva™ Device cleared for U.S. commercialization via K032843 on 2/27/200, the BD Insyte® Catheter(s), cleared for US commercialization via, K971339 on 12/24/1997 and the Retractable Technologies' VanishPoint® IV Catheter , cleared for US commercialization via K051355, on 9/23/2005.

Device Description:

The NovaCath™ Secure IV Catheter System is comprised of an over-the-needle, peripheral intravascular catheter made from a radiopaque slender, flexible plastic, integrated extension tubing with a secondary stabilization hub system, a female luer lock and clamp, and a passive needle shielding mechanism. The design of the NovaCath™ System is considered a closed system since it protects users from blood exposure during the catheter insertion procedure. The needle is withdrawn through a septum that will seal after the needle has been withdrawn and the luer lock is closed, blood is contained within the NovaCath™ System during insertion. 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.

Indications for Use:

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™ System may be utilized in any patient population with consideration given to vascular anatomy and appropriateness of procedure. The 18, 20 and 22 gauge NovaCath™ System catheters are suitable for use with power injectors for a maximum of 300 psi.

Comparison of Technological Characteristics:

The technological similarities between the subject NovaCath™ Secure IV Catheter System and the noted predicate devices are substantially equivalent. There are no new questions raised regarding safety or efficacy of the subject NovaCath™ Secure IV Catheter System. Table 1, below provides a summary comparison of the technological characteristics.

Table 1: Comparison Between NovaCath™ Secure IV Catheter System and Predicates

Technological SE Comparison				
Comparison Criteria	NovaCath™ Secure IV Catheter System	K032643 Nexiva™	K974339 Insyte®	K051355 VanishPoint®
Same Intended Use	Yes	Yes	Yes	Yes
Prescription Device (Rx Only)	Yes	Yes	Yes	Yes
Biocompatible Polyurethane Catheter	Yes	Yes	Yes	Yes
Biocompatible Materials of Fabrication	Yes	Yes	Yes	Yes
Closed System	Yes	Yes	No	No
Built-In Extension from Main Assembly	Yes, connecting tubing & reverse Y-configuration	Yes, connecting tubing & Y-configuration	No	No
Flashback Visualization	Yes, dual flash feature, allows for visualization at pre-priming & upon insertion	Yes, single, allows flash view upon insertion	Yes, single, allows flash view upon insertion	Yes, single, allows flash view upon insertion
Sharps Injury Prevention Feature	Yes, integrated sharps injury prevention device (passive)	Yes, integrated sharps injury prevention device	Yes integrated sharps injury prevention device	No, Automatic needle retraction occurs with depression of the needle housing
General Specifications	Yes, overall size is consistent w/ other IV catheter devices once extension tubing is added	Yes, overall size is slightly different than other IV catheter devices, due to Y-connector tubing & manual needle retraction	Yes, overall size is consistent w/ other IV catheter devices	Yes, overall size is consistent with other IV catheter devices
Intended anatomical location	Yes, peripheral vasculature	Yes, peripheral vasculature	Yes, peripheral vasculature	Yes, peripheral vein or artery
Distal End Configuration	Yes, Catheter & Needle consistent w/ ISO 10555-5	Yes, Catheter & Needle consistent w/ ISO 10555-5	Yes, Catheter & Needle consistent w/ ISO 10555-5	No, Hub w/ female locking luer fitting per ISO 594
Proximal End Configuration	Yes, female luer access port	Yes, female luer access port & open hub	Yes, Open hub	Yes, Tube w/ tapered tip & one outlet. No side ports
Flow Rate (ml/min)	Yes, 20G: 52.55 ml/min	Yes, 20G 45 ml/min	Yes, 20G: 65 ml/min	UNK
Mechanical	Needle retraction is manual	Needle retraction is manual	Stainless steel spring for needle retraction	Automatic needle retraction w/slight depression of the needle housing
Catheter Stabilization	Yes, primary & secondary stabilization (platform and wings) provide 360° stabilization	Yes, stabilization wings	Yes, available w/winged hub	No
EO Sterilization Method	Yes	Yes	Yes	Yes
Packaged Sterile, Single Use	Yes	Yes	Yes	Yes
Non-pyrogenic	Yes	Yes	Yes	Yes
Made without Latex Rubber?	Yes	Yes	Yes	Yes
Made without DEHP?	Yes	Yes	No	
Multiple Gauge Sizes & Needle Lengths	Yes	Yes	Yes	Yes
For use w/ Power Injectors up to 300 psi	Yes 18G,20G,22G; 24G contraindicated	Yes	Yes	No

Summary of Device Evaluation:

The NovaCath™ Secure IV Catheter System is substantially equivalent in device description, intended use, function, principle of operation, and basic composition to the predicate devices noted herein.

The NovaCath™ Secure IV Catheter System has been designed and tested to meet the requirements of relevant FDA consensus standards, voluntary standards and FDA regulations and guidance documents applicable to the subject and predicate devices. Results of the non-clinical testing support the conclusion of substantial equivalence to the NovaCath™ Secure IV Catheter System to the predicate devices noted herein.

Performance Testing:

The NovaCath™ Secure IV Catheter System has been designed and successfully tested to meet the applicable requirements outlined in *ISO 10555-1 Sterile, single use intravascular catheters – Part 1 General requirements* and *ISO 10555-5 Sterile, single use intravascular catheters – Part 5 Over-needle peripheral catheters.*

Biocompatibility Testing:

The NovaCath™ Secure IV Catheter System is classified as an external communicating, prolonged (24hrs to less than 30 days) circulating blood contact device. The device was successfully tested per the *FDA Blue Book Memorandum - #G95-1 Table 1 Initial Evaluation Test for Consideration* and relevant *ISO 10993* related biocompatibility standards to establish that the NovaCath™ Secure IV Catheter System meets the appropriate biocompatibility testing requirements.

Sterilization and Shelf-life Testing:

The NovaCath™ System will be released to market with a Sterility Assurance Level of 10^{-6}, per the requirements set forth in ANSI/AAMI/ISO 11135-2. The NovaCath™ System is intended for single use only and not intended for reuse or re-sterilization by the user. The maximum levels of residues of ethylene oxide and ethylene chlorohydrin will not exceed the limits presented in ISO 10993-7. Shelf-life and expiry dating meet the requirements of *ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, which is also supported by real-time shelf -life data.

Clinical Data:

A NovaCath™ Secure IV Catheter System simulated clinical use study was successfully conducted in accordance with *FDA Guidance for Medical Devices with Sharps Injury Prevention Features.*

No prospective clinical trials were conducted in support of this Traditional 510(k).

Conclusions:

Based on the information contained herein, we conclude the NovaCath™ Secure IV Catheter System is substantially equivalent to the noted legally marketed Predicate devices and is safe and effective for its intended use.

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

Ms. Kay Fuller, RAC
Vice President, Regulatory & Clinical Affairs
Tangent Medical Technologies, Incorporated
8170 Jackson Road, Suite A
Ann Arbor, Michigan 48103

JUL 20 2012

Re: K120839
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: July 3, 2012
Received: July 5, 2012

Dear Ms. 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 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120839

Device Name: NovaCath™ Secure IV Catheter System

Indications for Use:

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™ 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 up to a maximum of 300 psi.

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)

Patricia Boston for Richard Chapman
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120839