510(k) Summary

Onset Medical Corporation, *SoloPath*® Re-Collapsible Access System

This 510(k) summary is submitted in accordance with the requirements of 21 CFR 807, section 807.92.

General Information

Sponsor's Name and Address:	Onset Medical Corporation 13900 Alton Parkway, Suite 120 Irvine, CA 92618
Contact Person:	Joseph Bishop Vice President and Chief Operating Officer Onset Medical Corporation 13900 Alton Parkway, Suite 120 Irvine, CA 92618 (949) 716-1100
Date Summary Prepared:	April 19, 2013
Device Trade Name:	*SoloPath*®Re-Collapsible Access System
Product Code:	DYB
Regulation Number:	21 CFR 870.1340
Classification:	Class II
Common Name:	Catheter Introducer
Predicate Devices	• Onset Medical *SoloPath*® Balloon Expandable TransFemoral Introducer (K092014 and K100819) • GORE® DrySeal Sheath (K093791) • Cook® Extra Large Check-Flo® Introducer (Pre-Amendment device)

Description

The *SoloPath*® Re-Collapsible Access System is a cardiovascular device designed to be used as a guide for catheters and/or devices introduced into the femoral artery. The device is provided sterile for single use.

Testing was performed to demonstrate the *SoloPath*® Re-Collapsible Access System device is substantially equivalent to the predicate devices.

Onset Medical Corporation's *SoloPath*® Re-Collapsible Access System is a sterile, single use device. It consists of a flexible, reinforced polymer sheath with an external collapsible outer jacket and specially folded, radially-collapsed distal end (the Sheath) pre-mounted over a central balloon dilatation catheter (the Expander), and equipped with a proximal hub assembly incorporating a hemostasis valve. The folded distal region of the Sheath is small in diameter, thus facilitating passage through the vessel. The SoloPath Assembly is inserted percutaneously into the femoral artery, over a guidewire, with the deflated Expander in place. Once positioned into the artery, the Expander balloon, when inflated with liquid, exerts controlled radial force, enlarging the folded distal region of the Sheath and surrounding anatomy. The Expander balloon is deflated and the Expander is removed leaving a large central lumen extending from the proximal end to the distal end of the Sheath, which maintains its expanded size by means of malleable distal reinforcement. The Sheath is designed as a guide for catheters and/or devices

introduced into the femoral artery. Prior to removal, the outer jacket is activated with liquid under low pressure, collapsing the outer sheath diameter for ease of removal.

The *SoloPath*® Re-Collapsible Access System is equivalent to approved predicate devices currently available as vascular introducers such as the Cook® Extra Large Check-Flo® Introducer which is available in 20F, 22F and 24F configurations with a variable usable lengths and Onset Medical Corporation's *SoloPath*® Balloon Expandable TransFemoral Introducer which utilizes the same material and balloon expandable dilation feature for vascular introduction. These devices are designed to be advanced over a guidewire, under fluoroscopic or ultrasound guidance. The dilator portion of the introducer assembly is advanced gently into the vasculature and facilitates a clinical conduit through which interventional tools and prostheses can be safely delivered. The devices may contain various hemostasis valve assemblies and hydrophilic-coated surfaces for improved lubricity. The *SoloPath*® Re-Collapsible Access System is equivalent in regards to materials, indications for use and overall clinical utility. However, like the approved *SoloPath*® TransFemoral Introducer, the *SoloPath*® Re-Collapsible Access System consists of a flexible sheath with a specially folded distal segment pre-mounted over a central balloon dilatation catheter (the Expander). The folded distal region of the Sheath is small in diameter, thus facilitating passage through the vessel. The *SoloPath*® Re-Collapsible Access System is inserted percutaneously into the femoral artery, over a guidewire. Once the device is positioned, the Expander balloon is inflated with liquid and exerts controlled radial dilation, enlarging the folded distal segment of the Sheath to a uni-diameter configuration. The Expander balloon is deflated and is removed leaving a large central lumen extending from the proximal end to the distal end of the Sheath. The *SoloPath*® Re-Collapsible Access System performs the same as previously approved predicate devices and raises no new issues of safety or effectiveness.

The sheath is capable of expanding and actively collapsing.

In Vitro bench studies were conducted to demonstrate that the *SoloPath*® Re-Collapsible Access System performed as intended in simulated use conditions. Biocompatibility testing was conducted to demonstrate conformance to ISO 10993-1 requirements.

Intended Use/Indications For Use

The *SoloPath*® Re-Collapsible Access System is intended to be inserted percutaneously into the femoral artery, over a guidewire and once expanded, to provide a guide for catheters and/or devices introduced into the femoral artery.

Comparison of the Technological Characteristics of the New Device and Predicate Devices

Device Name	*SoloPath*® Re-Collapsible Access System	*SoloPath*® Balloon Expandable TransFemoral Introducer	GORE® DrySeal Sheath	Extra Large Check-Flo® Introducer
K#	K121404	K092014 and K100819	K093791	Pre-Amendment device
Manufacturer	Onset Medical Corporation	Onset Medical Corporation	Gore Medical	Cook Incorporated
Indication for use	The *SoloPath*® Re-Collapsible Access System is intended to be inserted percutaneously into the femoral artery, over a guidewire and once expanded, to be used as a guide for catheters and/or devices introduced into the femoral artery.	The *SoloPath*® Balloon Expandable TransFemoral Introducer is intended to be inserted percutaneously into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters and/or devices introduced into the femoral iliac arteries.	The GORE DrySeal Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.	Introducers are intended for introduction of balloons, closed and non-tapered end catheters or other diagnostic or interventional devices. The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths should be employed
Device Name	New Device: *SoloPath*® Re-Collapsible Access System	Predicate Device: *SoloPath*® TransFemoral Introducer	Predicate Device: GORE® DrySeal Sheath	Predicate Device: Extra Large Check-Flo® Introducer
Placement	Standard techniques for placement of vascular access sheaths	Standard techniques for placement of vascular access sheaths	Standard techniques for placement of vascular access sheaths	Standard techniques for placement of vascular access sheaths

Device Name	*SoloPath*® Re-Collapsible Access System	*SoloPath*® Balloon Expandable TransFemoral Introducer	GORE® DrySeal Sheath	Extra Large Check-Flo® Introducer
Guidewire compatibility	Can be navigated over a .035" or .038"compatible guidewire	Can be navigated over a .035" or .038"compatible guidewire	Recommended to be navigated over a .035" or smaller guidewire.	Recommended to be navigated over a .035" guidewire.
Radiographic markers	Sheath tip = Radiopaque Gold Distal Marker	Sheath tip = Radiopaque Gold Distal Marker	Sheath tip = distal marker band	Optional
Shaft Materials	• Medical grade plastic shaft reinforced with stainless steel ribbon • PET Outer Jacket • Coated with hydrophilic coating	• Medical grade plastic shaft reinforced with stainless steel ribbon • Coated with hydrophilic coating	• Medical grade plastic shaft • Physical characteristics are similar to other predicate devices.	• Medical grade plastic shaft
Device length	25cm – 35cm	25cm – 35cm	28cm	25cm – 55 cm
Available sheath ID's (pre-expansion)	19F – 24F	11F – 21F	12F – 26F	18F – 24F
Available sheath OD's (post-expansion)	23F – 28.5F	14 F – 24 F	NA	NA
Fixed OD (guidewire lumen)	Yes	Yes	Yes	Yes
Variable OD (Capable of expansion)	Yes – via injecting fluid though the applicable port	Yes – via injecting fluid though the applicable port	No	No
Capable of OD collapsation	Yes – by injecting fluid into the applicable port	Yes – passively; the sheath collapses during removal	No	No
Sterilized by	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

Performance Testing

Results of bench studies conducted on both the 19Fx35 cm and 24Fx35cm the *SoloPath*® Re-Collapsible Access System demonstrated the System to be as safe and effective as the predicate device based on the biocompatibility of the materials used, sterilization validation, bench testing. Testing was performed on both EO processed and EO equivalent product, and product accelerated aged to 6 months.

The following studies were conducted and acceptance criteria were met:

Functional Verification

- Bend
- Coating integrity
- Coating particulate
- Collapsation
- Dilator burst
- Dilator cycle
- Expansion
- Hemostasis valve leakage
- Sheath jacket burst
- Sheath jacket cycle
- Tensile
- Torque
- Trackability

Materials tested per ISO 10993-1

- Cytotoxicity
- Complement Activation
- Partial Thromboplastin Time (PTT)
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogenicity, and
- Hemolysis

Conclusion

- The *SoloPath*® Re-Collapsible Access System is substantially equivalent to the predicate devices.
- The indication for use for the devices is substantially equivalent.
- The technological design and functional characteristics of the sterile disposable access devices are all substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 3, 2013

Onset Medical Corporation
Mr. Joseph Bishop
Vice President and Chief Operating Officer
13900 Alton Parkway, Suite 120
Irvine, CA 92618

Re: K121404
Trade/Device Name: SoloPath® Re-Collapsible Access System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 19, 2013
Received: April 24, 2013

Dear Mr. Bishop:

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 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. 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,

Bram D. Zuckerman

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 (if known): **K121404**

Device Name: *SoloPath*® Re-Collapsible Access System

Indications for Use:

The SoloPath® Re-Collapsible Access System is intended to be inserted percutaneously into the femoral artery, over a guidewire and once expanded, to provide a guide for catheters and/or devices introduced into the femoral artery.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman
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