**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 5, 2016

Onset Medical Corporation
% Monika McDole-Russell, MSRA, RAC
Senior Regulatory Affairs Specialist
Terumo Corporation
265 Davidson Ave, Suite 320
Somerset, NJ 08873

Re: K152498
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: December 3, 2015
Received: December 4, 2015

Dear Ms. McDole-Russell:

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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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 on last page.*

510(k) Number *(if known)*
K152498

Device Name
SoloPath® Re-Collapsible Access System

Indications for Use *(Describe)*
The SoloPath® Re-Collapsible Access System is indicated for percutaneous insertion into the femoral artery over a guidewire and, once expanded, to provide a guide for catheters and/or devices introduced into the femoral artery. The device may also be used to expand femoroiliac artery lesions to facilitate its use as an Access System.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) SUMMARY

## A. SUBMITTER INFORMATION (807.92(a)(1))

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**Date prepared:** January 4, 2016

## B. DEVICE NAME (807.92(a)(2))

| | |
|---|---|
| *Proprietary Name:* | SoloPath® Re-Collapsible Access System |
| *Common Name:* | Catheter introducer |
| *Classification Name:* | Catheter Introducer |
| *Classification Panel:* | Cardiovascular |
| *Regulation:* | 21 CFR 870.1340 |
| *Product Code:* | DYB |
| *Classification:* | Class II |

## C. PREDICATE DEVICE (807.92(a)(3))

Substantial equivalence is claimed to the following legally marketed device:

- K121404 SoloPath Re-Collapsible Access System, manufactured by Onset Medical, California (a division of Terumo Medical Corporation).

## D. REASON FOR 510(K) SUBMISSION

This 510(k) is being submitted for:

1. The addition of a secondary indication to the previously cleared indication for the device (K121404).
2. Minor grammatical and punctuation changes to the wording of the primary indication, as depicted in the table below (re-worded section in **bold** font).

| Wording of currently cleared (primary) indication (K121404) | Proposed wording for primary indication |
|---|---|

| | |
|---|---|
| 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. | The SoloPath® Re-Collapsible Access System is **indicated for percutaneous insertion** into the femoral artery over a guidewire and**,** once expanded**,** to provide a guide for catheters and/or devices introduced into the femoral artery. |

The changes to the wording are for clarity and conciseness only and do not alter the currently cleared indication for use in any way.

## E. DEVICE DESCRIPTION (807.92(a)(4))

The SoloPath Re-Collapsible Access System is a sterile, single-use device that consists of a flexible, reinforced polymer sheath 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 SoloPath assembly is inserted percutaneously over a guidewire, with the deflated Expander in place. Once positioned into the vasculature and inflated with liquid, the Expander balloon exerts a 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 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 SoloPath Re-Collapsible Access System features an integrated external collapsible outer jacket which is pressurized with liquid under low pressure prior to removal, collapsing the outer sheath diameter for ease of removal. The Sheath is designed: 1) as a guide for catheters and/or devices introduced into the femoral artery and 2) to dilate stenosed femoro-iliac vessels as an adjunct to its primary function.

The principles of operation for the subject SoloPath Re-Collapsible Access System are identical to those of the currently cleared SoloPath Re-Collapsible Access System (K121404). There are no changes to the insertion, deployment, or removal of the device as a result of this secondary indication.

## F. INTENDED USE (807.92(a)(5))

The SoloPath® Re-Collapsible Access System is indicated for percutaneous insertion into the femoral artery over a guidewire and, once expanded, to provide a guide for catheters and/or devices introduced into the femoral artery. The device may also be used to expand femoroiliac artery lesions to facilitate its use as an Access System.

## G. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

The SoloPath Re-Collapsible Access System, the subject of this Traditional 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to K121404 SoloPath Re-Collapsible Access System, manufactured by Onset Medical, California (a division of Terumo Medical Corporation).

The SoloPath Re-Collapsible Access System was cleared for its primary indication via K121404; no significant design, material or manufacturing changes have occurred since that clearance and no changes are being made to the primary indication for intended use as a result of this submission. Therefore, this submission focuses solely on the use of the device for the proposed secondary indication.

A comparison of the intended use/indications for use and technological characteristics relevant to the secondary indication are summarized in the table on the following page. The primary indication is not changing; the secondary indication does not impact the safety and effectiveness of the device; there are no changes to the insertion, deployment, or removal of the device as a result of this secondary indication.

*Note: A statement of substantial equivalence to another product is required by 21CFR807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is, therefore, not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "…a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977)*

**Table 5.1: Device Comparison Chart**

| **Device Characteristic** | **Subject Device:** SoloPath Re-Collapsible Access System | **Predicate:** SoloPath Re-Collapsible Access System (K121404) |
|---|---|---|
| ***Manufacturer*** | Onset Medical, a subsidiary of Terumo Corporation | Same |
| ***Intended Use*** | The SoloPath® Re-Collapsible Access System is indicated for percutaneous insertion into the femoral artery over a guidewire and, once expanded, to provide a guide for catheters and/or devices introduced into the femoral artery. The device may also be used to expand femoroiliac artery lesions to facilitate its use as an Access System. | 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. |
| ***Operation Principle*** | Manual | Same |
| ***Design / Construction*** | • Sheath assembly (sheath, expander, fairing tip, flush lines, ports, and hemostasis valve) | • Same |

| **Device Characteristic** | **Subject Device:** SoloPath Re-Collapsible Access System | **Predicate:** SoloPath Re-Collapsible Access System (K121404) |
|---|---|---|
| ***Materials*** | • Dilator assembly – Polycarbonate, Polypropylene, Silicone rubber, Polycarbonate, Hytrel, PET, Polyurethane, ABS<br>• Sheath Assembly – Hytrel, 304 stainless steel, Gold, PET, Adhesive, Polycarbonate, Polypropylene<br>• Sheath Hemostasis Valve Assembly – Polycarbonate, Silicone, Polypropylene, Adhesive | • Same |
| ***Package*** | • Package support (cardboard)<br>• Chevron pouch<br>• Shelf box | • Same |

| Device Characteristic | | **Subject Device:** SoloPath Re-Collapsible Access System | **Predicate:** SoloPath Re-Collapsible Access System (K121404) |
|---|---|---|---|
| ***Specifications*** | ***Length of inflatable portion (balloon)*** | 20-30 cm (200-300 mm) | Same |
| | ***Recommended Guidewire size*** | 0.038” or smaller | Same |
| | ***Maximum Inflated O.D.*** | 28.5 Fr (9.50 mm)[1] | |
| | ***Introducer size/Insertion profile*** | 13.5 -15 Fr[2] | |
| | ***Rated Burst Pressure*** | 20 atm (2026 kPa) | |
| ***Sterilization*** | | Ethylene Oxide | |

1. Maximum expanded/inflated O.D. provided for SoloPath Re-Collapsible outer sheath. Expander is not intended to be used in patient without the outer sheath;

2. Actual insertion profile of the SoloPath Re-Collapsible device.

## H. NON CLINICAL TESTS (807.92(b)(1))\

***Performance***

Performance testing was conducted to demonstrate substantial equivalence to the predicate device. No new issues of safety and effectiveness were raised during testing.

Terumo consulted ISO 10555-4:2013 *Sterile, Single-Use Intravascular Catheters - Part 4: Balloon Dilatation Catheters* while preparing this submission and confirmed that all testing applicable to this device was successfully completed (reference Section 18). No deviations from this recognized consensus ISO standard were identified in the testing.

Only those tests pertinent to the secondary indication are discussed in this submission; a brief summary of that testing is included below. Testing is discussed in detail in Section 18 – Performance Testing (Bench).

**Table 5.2: Testing Performed on the SoloPath Re-Collapsible Device**

| Test | Relevant Section of ISO 10555-4 |
|---|---|
| Radio-detectability | Section 4.2 |
| Designation of nominal size | Section 4.3 |
| Balloon rated burst pressure (RBP) | Section 4.4.1, Annex A |
| Balloon fatigue; freedom from leakage and damage on inflation | Section 4.4.2, Annex B |
| Balloon deflation time | Section 4.4.3, Annex C |

Performance testing demonstrates that the SoloPath Re-Collapsible Access System conforms to the recognized consensus ISO standard, is substantially equivalent to the predicate device, and is acceptable for clinical use throughout the shelf life.

***Biocompatibility***

No changes have been made to the materials, sterilization process or packaging of the SoloPath Re-Collapsible Access System since the original biocompatibility testing performed in accordance with ISO 10993, the results of which were reviewed under K121404.

***Sterilization***

The sterility of the device is assured using an overkill/half-cycle sterilization method validated in accordance with ISO 11135-1:*2007 Sterilization of health care products -- Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*. The SoloPath Re-Collapsible Access System is sterilized to provide a Sterility Assurance Level (SAL) of $10^{-6}$.

No changes have been made to the sterilization process or procedure since the device was cleared under K121404.

***Risk Analysis***

A Product Risk Analysis was conducted in accordance with ISO 14971, taking into account the modifications to the device since clearance under K121404, and it was determined that any new risks were adequately captured and mitigated.

## I. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

## J. CONCLUSION (807.92(b)(3))

In summary, the SoloPath Re-Collapsible Access System, the subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, performance and overall clinical utility to K121404 SoloPath Re-Collapsible Access System, manufactured by Onset Medical, California (a division of Terumo Medical Corporation).

There is no significant difference that raises any new issues of safety and effectiveness.