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 17, 2016

SiO_2 Medical Products
c/o Mr. Paul Dryden
Consultant
350 Enterprise Drive
Auburn, Alabama 36830

Re: K153553
Trade/Device Name: SiO_2 Coated Syringe 3 mL
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 15, 2016
Received: April 18, 2016

Dear Mr. Dryden:

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,

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)*

K153553

Device Name

SiO_2 Coated Syringe 3 mL

Indications for Use *(Describe)*

The SiO_2 Coated Syringe 3 mL is intended to be used to inject fluids into, or withdraw fluids from, the body.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

16-May-16

SiO_2 Medical Products
350 Enterprise Drive
Auburn, Alabama 36830

Tel – 334-321-5060
Email: randy.crenshaw@sio2med.com

Official Contact: Randy Crenshaw
Director of Quality and Regulatory

Proprietary or Trade Name: SiO_2 Coated Syringe 3 mL

Common/Usual Name: Syringe, Piston

Classification Name/Code: FMF – Syringe, Piston
21 CFR 880.5860
Class II

Device: SiO_2 Coated Syringe 3 mL

Predicate Device: K110771 – Becton Dickinson – Single Use syringe

Reference Device: K111091 - Merit Medical Syringe

Device Description:
SiO_2 Coated Syringe 3 mL is a plastic disposable standard 3 mL piston syringe without needle is made of a cyclic olefin polymer (COP) and coated internally with silica glass layers. The layer is deposited by plasma enhanced chemical vapor deposition (PECVD) process.

This is a standard 3 mL single use, disposable syringe without needle.

Indications for Use:
The SiO_2 Coated Syringe 3 mL is intended to be used to inject fluids into, or withdraw fluids from, the body.

Contraindications

- Do not use this syringe with sesame oil-based drugs.
- Do not use this syringe with non-polar solvents.

Discussion of Substantial Equivalence

Table 1 – Substantial Equivalence Comparative Table

Element of Comparison	Subject Device	Becton Dickinson Single Use Syringe K110771
Syringe Type	Piston Syringe - FMF	Piston Syringe - FMF
Intended Use(s)	The SiO2 Coated Syringe 3 mL is intended to be used to inject fluids into, or withdraw fluids from, the body.	For use by health care professionals for general purpose fluid aspiration/injection.
Length	82.77mm	79.3 – 80.7mm
Barrel diameter	ID: 8.62mm OD: 11.34mm	ID: 8.5 – 8.7mm OD: 10.0 – 10.2mm

Element of Comparison	**Subject Device**	**Becton Dickinson Single Use Syringe K110771**
Finger Grip Size and Shape	Length: 24.64 – 25.14mm Width: 14.43 – 14.93mm Thickness: 1.85 – 2.11mm	Length: 24.33 - 24.59mm Width: 12.57 – 12.83mm Thickness: 1.85 – 2.11mm
Tip type	Centric – male luer lock Complying with ISO 594-1, -2	Centric - male luer lock Complying with ISO 594-1,-2
Volume	3 mL	3 mL Plus various sizes
Barrel marking specs	Complies with ISO 7886-1	Complies with ISO 7886-1
Graduations legibility	Legible	Legible
Lubricant type	Silicone	Silicone
Plunger Operation (Fi and Fm Forces)	Plunger Withdraw: Fi=2.11 N, Fm=2.39 N Plunger Deploy: Fi=2.35 N, Fm=0.58 N	Plunger Withdraw: Fi=1.18 N, Fm=1.48 N Plunger Deploy: Fi=2.21 N, Fm=1.68 N
Barrel transparency	Transparent and Clear	Transparent and Clear
Delivery accuracy	Complies with ISO 7886-1	Complies with ISO 7886-1
Labeling	ISO 7886-1 ISO 15223-1 21 CFR Part 801	ISO 7886-1 21 CFR Part 801
Sterilization	E-beam Irradiation sterilization 25KGy; achieving 10-6 SAL	Ethylene Oxide or Irradiation sterilization 10-6 SAL
Shelf-life and Age testing	12 months empty	
Mechanical and environmental stressors	Mechanical force Freeze / thaw testing	
Verification of coating chemistry	Using FTIR Microscopy Test Method	

The subject device is viewed as substantially equivalent to the predicate device because:

Indications for Use – The proposed indications for use are similar, in that they are to be used to inject fluids into, or withdraw fluids from, the body, also referred to as general purpose fluid aspiration/injection.
Discussion - The indications for use are similar for the subject device and the predicate – K110771 – BD single use syringe.

Technology – The basic design of the subject device is similar as the subject device complies with ISO 7886-1.
Discussion – The basic technology of a plunger style syringe is identical to the predicate. The technology of applying a glass coating to the inside of the barrel is different than the predicate but we have demonstrated that its performance is equivalent and complies with ISO 7886-1 as does the predicate - K110771 - BD Single Use Syringe. The difference in technology has been evaluated and do not raise any new questions related to risk, safety, or effectiveness.

Materials – The materials in fluid contact have been evaluated in accordance to the suggestions of ISO 7886-1 and ISO 10993-1 and G95-1 which consider the patient contact as Externally communicating, Circulating blood with Limited duration (<24 hours).

We evaluated the subject device utilizing the following tests:

- Cytotoxicity: Elution Test, Serum Supplemented MEM Extract
- Skin Sensitization Test Protocol, Guinea Pig Maximization Test
- Intracutaneous (Intradermal) Reactivity Test
- Systemic Toxicity: Saline and Vegetable Oil Extracts
- Hemolysis Test (NIH Method) Saline Extract
- Extractable and Leachables as described in ISO 7886-1 coated / uncoated
- USP Rabbit Pyrogen Test (Material Mediated)
- Bacterial Endotoxin-Mediated Pyrogen test (Limulus Amebocyte Lysate Test)

Discussion - We performed the applicable testing for biocompatibility and the materials were found to be non-reactive. We have made reference to the Merit Medical Syringe K111091 which has similar indications for use and the barrel is made of Cyclo-olefin polymer. We included this reference device to support that the Cyclo-olefin polymer is not a new material for use in syringes.

Non-clinical Testing

We performed bench testing to demonstrate that the subject device meets the ISO 7886-1 and other applicable standards. Testing included:

Standard and Tests Performed
ISO 7886-1- Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use
Section 5, Cleanliness Section 6 & Annex A, Limits for Acidity or Alkalinity Section 7 & Annex A, Limits for Extractable Metals Section 8, Lubricant Section 9, Tolerance on Graduated Capacity Section 10.1, Scale Section 10.2, Numbering of Scale Section 10.3, Overall Length of Scale to Nominal Capacity Line Section 10.4, Position of Scale Section 11.1, Dimensions Section 11.2, Finger Grips Section 12.1, Design Section 12.2, Fit of Piston in Barrel Annex G, Force to Operate Section 12.3, Fiducial Line Section 13.2, Position of Nozzle on End of Barrel Section 13.3, Nozzle Lumen Section 14.1 - Annex C, Dead Space Section 14.2 - Annex D, Liquid Leakage Compression Section 14.2 - Annex B, Air Leakage past Syringe Piston during Aspiration
ISO 594 – 1 and -2 - Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1 and Part 2
Section 5.1, Gauging Section 5.2, Liquid Leakage

Section 5.3, Air Leakage Section 5.4, Separation Force Section 5.5, Unscrewing Torque Section 5.6, Ease of Assembly Section 5.7, Resistance to Overriding Section 5.8, Stress Cracking
ASTM D4169-14; Standard Practice for Performance Testing of Shipping Containers and Systems
Manual handling – drop test and second Drop Sequence
Vehicle stacking
Loose Load Vibration
Vehicle Vibration
Concentrated Impact

- ASTM F1980-07 (2011); Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- Real-time aging - 24 months
- Oxygen Transmission Rate ("OTR")
- Container compatibility with certain drug products
- Mechanical stressor
- Environmental stressor - freeze-thaw study Summary
- Ink adhesion and Wipe & Tape Test Report
- Plunger Force Test
- Physical Characteristics Test
- Syringe Dimensions
- Plunger Force Test
- FTIR Test method for coating chemistry

Substantial Equivalence Conclusion –
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the SiO_2 Coated Syringe 3 mL and is substantially equivalent to the predicate device.