Marz Medical, Inc.
Blossom Delivery Assist Device
K131692
510K Notification

JUL 10 2014

IV. 510(k) Summary

Marz Blossom Syringe Assist Device

Submitter/Sponsor's Name, Address, Telephone Number, Contact Person and Date Prepared

Marz Medical, Inc.
2500 Hospital Drive, Bldg 9
Mountain View, CA 94040

Contact Person:
C/O Mary Pascual Gallup
VP of Regulatory Affairs

Phone: 510-441-4017 (Direct Line)
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Date Prepared: 06/02/2013

Name of Device: Marz Blossom Syringe Assist device

Common or Usual Name: Tissue Expander Accessory (Syringe Assist, Accessory)

Classification Name

Classification:	Unclassified
Class:	Unclassified
Classification Name:	Tissue Expander Accessory

Predicate Device

The Marz Blossom Syringe Accessory System is substantially equivalent to its predicate McGhan Tissue expander Fill Kit (K853014) commercially available via the FDA 510(k) Pre-Market Notification with regards to intended use, design, materials and technology. The Marz Blossom Syringe Assist device does not raise new questions associated with safety and efficacy relative to such commercially available medical devices.

Indications for Use

The Marz Blossom Syringe Assist device is intended to be used to assist the clinician in the delivery of sterile saline to fill temporary, removable tissue expanders in accordance with the

best judgment of the clinician. Specifically, the Marz Blossom Syringe Assist device is indicated for assisting the clinician in delivery of sterile saline into the surgically placed sub-dermal temporary, removable tissue expander.

Device Description

1. The Marz controller is a battery operated device that is used to assist the clinician in delivering sterile saline into a surgically placed sub-dermal temporary, removable tissue expander. The Marz Blossom Syringe Assist device includes a battery powered controller to provide a regulated method for delivery of a specific volume of saline at a specific rate. The Marz controller is compatible with 10cc plastic luer lock piston barrel syringe. The Marz Medical Blossom Syringe Assist Device consists of a re-useable controller with an integrated syringe cradle for holding a 10cc syringe, firmware, LED displays, an external pressure sensor, and is battery powered by three 1.5V, AA batteries (LR6 designation).

2. Supplied with the controller in a kit are the following components: Single use, sterile 10cc luer lock piston syringe, transfer set with proximal connection to the controller, and saline reservoir including distal connections to the inflation port of the expander, or via an infusion needle. All connections are luer lock compatible. The fluid path is clear that allows for visual inspection of the content.

Technological Characteristics

The Marz controller is a battery operated device that is used to assist the clinician in delivering sterile saline into a surgically placed sub-dermal temporary, removable tissue expander. The Marz Blossom Syringe Assist device includes a battery powered controller to provide a regulated method for delivery of a specific volume of saline at a specific rate. The Marz controller is compatible with 10cc plastic luer lock piston barrel syringe. The Marz Medical Blossom Syringe Assist Device consists of a re-useable controller with an integrated syringe cradle for holding a 10cc syringe, firmware, LED displays, an external pressure sensor, and is battery powered by three 1.5V, AA batteries (LR6 designation).

The Marz Blossom Syringe Assist device controller has been evaluated for and has passed criteria for safety and performance testing. The Marz Blossom Syringe Assist device has also passed design verification and validation testing criteria in accordance with internal company controls and design control procedures to support the safety and intended use of the product.

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Performance Testing Conducted

The following tests were completed and reported results are summarized.

Reference No./Description	Report Title	Overall Results
MRZ-TR-881 – Verify software will respond as designed under normal operating conditions.	Fluid Delivery System (FDS) Firmware/Software Verification Test Report	The units were subjected to software verification testing under normal use and normal conditions, all units passed the testing.
MRZ-TR-882 – Verify the device can deliver saline to the tissue expander within the parameters of the specification.	Performance Verification Test Report	The devices were subjected to delivery of saline in their typical operating modes and specifications. All units passed testing.
MRZ-TR-880 – Verify packaging can withstand shipping conditions without damage or loss of function to the device. This testing included: • Preconditioning. • Compression • Shock/Drop • Vibration Testing • Functional	ISTA 2A Packaging Test, Blossom System	The device was subjected to std transit testing which included: • Preconditioning. • Compression • Shock/Drop • Vibration Testing. The device were not damaged and remained functional after testing. The unit passed.
MRZ-TR-886 – Verify tubing set adaptor accessory can be stored for 6 months without loss of sterility. This testing included: • Tensile Test of pouch. • Dye Penetration of the pouch.	6 Month Shelf Life	The devices were subjected to accelerated aging at elevated temperatures to simulate 6 month shelf life. All units passed all testing.

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Reference No./Description	Report Title	Overall Results
• Tensile Test of joints found in the accessory assemblies.		
MRZ-TR-883 – The purpose of this test was to compare actual thumb pressure to depress a 10ml syringe vs. the force generated by the automated system to depress a 10ml syringe.	Thumb Force Test Report	Pass, force applied during injection is substantially equivalent to manual approach (thumb pressure)
Notebook Testing The purpose of this test was to quantify the pressures the 10cc Luer Lock syringe with automatic spring return dispensing system could generate by depressing the plunger and the forces required to recycle the dispensing system. Additional tests were conducted to determine max force and pressure generated by the Marz device. Lastly, Forces required to depress the plunger and max. pressure for 10cc and 60cc single piston syringe without automatic return vs. the Marz device.	Comparative Product Analysis and System Forces and Pressures	Summary: The Blossom Syringe Assist device requires less force & pressure to dispense fluid than the 60cc syringe, and its predicate, McGhan Tissue fill kit.
MRZ-TR-955 – Verify that the software fault	Marz Medical, Inc. Fluid Delivery System Fault	All fault conditions were verified, and the device

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Reference No./Description	Report Title	Overall Results
conditions were verifiable during testing.	conditions test Report.	responded as designed. The unit passed the verification testing.
EMC FCC Part 15 Subpart B		Pass
IEC 60601 Part 1: 1990, Amd A1:1993, A11: 1993, A12; 1993; A2: 1995 and A13: 1996		Pass

Substantial Equivalence

The Marz Blossom Syringe Assist device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device The McGhan Tissue Fill Kit (K853014). Both systems have two, one-way valves that prevent backflow into the fluid source, which is the saline bag. After a specified volume is delivered, both devices have an automatic refill feature. The technological differences between the Marz Syringe Assist/Accessory System and its predicate device raises no new issues of safety or effectiveness.

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

July 10, 2014

Marz Medical Incorporated
Ms. Mary Pascual Gallup
Vice President of Regulatory Affairs
2500 Hospital Drive, Building 9
Mountain View, California 94040

Re: K131692
Trade/Device Name: Marz Blossom Saline Delivery Assist device
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LCJ
Dated: June 6, 2014
Received: June 9, 2014

Dear Ms. Gallup:

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" (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 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K131692

Device Name
Blossom Syringe Assist Device

Indications for Use *(Describe)*

The Marz Blossom Syringe Assist device is intended to be used to assist the clinician in the delivery of sterile saline to fill temporary, removable tissue expanders in accordance with the best judgment of the clinician. Specifically, the Marz Blossom Syringe Assist device is indicated for assisting the clinician in delivery of sterile saline into the surgically placed sub-dermal temporary, removable tissue expander.

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)*

Joshua C. Nipper -S

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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