November 8, 2017

Mazza Healthcare, LLC.
% Jon Gilbert
Regulatory Consultant to Mazza Healthcare, LLC
Jon Gilbert
1641 Jeurissen Lane
Chanhassen, Minnesota 55317

Re: K171131
Trade/Device Name: MHC Standard and NRFit™ Tip Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: September 29, 2017
Received: October 2, 2017

Dear Jon Gilbert:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171131

Device Name

MHC Standard and NRFit™ Tip Syringes

Indications for Use *(Describe)*

The MHC Standard and NRFit™ Tip Syringes are intended to inject fluids into or withdraw fluids from the body.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Section 5. 510(k) Summary

Submitter

Sponsor: Mazza Healthcare, LLC
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Bannockburn, IL 60015

Contact: Jon Gilbert, Consultant
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jgilb.raca@gmail.com

Date of Preparation: September 29, 2017

Subject Device:

Common Name:	Standard and Neuraxial Tip Syringes
Trade Name:	MHC Standard and NRFit™ Tip Syringes
Regulation Number:	21 CFR 880.5860
Regulation Name:	Piston syringe
Review Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	FMF
Primary Predicate: 510(k):	Vesco Medical NRFit™ Tip Syringes K170218 cleared February 24, 2017
Predicate Device: 510(k):	DMC Medical Single-Use Polycarbonate Syringe K103736 cleared June 10, 2011

Device Description:
The MHC Standard and NRFit™ Tip Syringes are provided sterile or in bulk non-sterile for further processing (e.g., sterilization). They are single use devices consisting of rigid polycarbonate barrels and plungers with a synthetic rubber gasket. The syringe barrels with neuraxial tips are ISO 80369 - 6 compliant and allow for connections of neuraxial specific applications while reducing the likelihood of misconnections to non-neuraxial devices. The syringe barrels are printed with graduated markings in cc (milliliters) indicating the volume of liquid inside the syringe barrel. The proposed models for the standard and neuraxial devices are listed below in Table 1.

Table 1. MCH Models and Description

MHC Model #	Item Description
09-050-WH	5cc Polycarbonate Luer Slip Tip Syringe W/Silicone
09-060-WH	5cc Polycarbonate Luer Lock Tip Syringe W/Silicone
09-055-WHN	5cc Polycarbonate Neuraxial Slip Tip Syringe W/Silicone
09-010-WH	10cc Polycarbonate Luer Slip Tip Syringe w/Silicone
09-120-WH	10cc Polycarbonate Luer Lock Tip Syringe w/Silicone
09-015-WHN	10cc Polycarbonate Neuraxial Slip Tip Syringe w/Silicone

A difference between the predicate syringe (K103736) without a neuraxial tip and the subject syringe with a neuraxial tip is the design of the needle´s hub. While the predicate devices (K103736) are designed with a luer slip tip (taper) or luer lock connector the subject neuraxial devices are equipped with a NRFit™ neuraxial connection as standardized in ISO 80369-6. Additionally, the NRFit™ Tip Syringe piston is yellow.

The clinical technique, indications for use, technical specifications, materials used, and sterility status (validation and sterility assurance level) are identical between the subject and predicate Standard syringes. As stated above, the NRFit™ tip syringes provides connections of neuraxial specific applications while reducing the likelihood of misconnections to non-neuraxial devices

Indications for Use:
The MHC Standard and NRFit™ Tip Syringes are intended to inject fluids into or withdraw fluids from the body.

Performance Testing:
The performance of the subject MHC Standard Tip Syringes is identical to the predicate devices as no material (with the exception of the yellow piston), manufacturing or technological changes have occurred. The performance of the subject MHC NRFit™ Tip Syringes is similar to the predicate neuraxial syringes (K170218) as both designs are based upon ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications.*

Non-Clinical Tests
Verification and validation testing was performed with the subject neuraxial (NRFit) Tip Syringes. It was found that subject neuraxial (NRFit) Tip Syringes are in compliance with design and performance requirements according to ISO 80369-6:2016 “Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications,” and ISO 80369-20:2016 “Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common Test Methods, including Visual Inspection (burrs, hooks, cracks, foreign contamination, missing components), Stress Cracking per ISO 80369-6 (sec. 6.3) and ISO 80369-20 (Annex E), Fluid Leakage by Pressure Decay per ISO 80369-20 (Annex B), Subatmospheric Pressue Air Leakage per ISO 80369-20 (Annex D), and, Resistance to Separation from Axial Load per ISO 80369-20 (Annex F). Biocompatibility testing has demonstrated the subject devices meet the guidelines as described in the FDA guidance document entitled, “Use of International Standard ISO10993-1, " Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Clinical and Animal Tests
Clinical tests were not required to demonstrate performance of between the subject and predicate devices. Product functionality has been adequately assessed by non-clinical tests.

Table 2. Technological Characteristics & Substantial Equivalence

Component:	Vesco Medical K170218	DMC Medical, Ltd, K103736	MHC Standard and Neuraxial*
Syringe Barrel:	Polypropylene	Polycarbonate	Polycarbonate
Plunger Tip:	Synthetic Rubber	Elastomer	Elastomer
Plunger	Polypropylene	ABS polymer	ABS polymer
Syringe Piston Lube Coating	Polydimethylsiloxane, Silanol Terminated	Medical Grade Oil	Medical Grade Oil
Calibrated Barrel Volume:	Yes	Yes	Yes
Recommended Sterilization method:	EtO	EtO	EtO
510(k) Approval	K170218	K103736	K171131

*Subject device Standard and NRFit components are comprised of same materials and manufactured using same manufacturing methods. K103736 best represents predicate materials and components while K170218 and ISO 80369-6 represents requisite neuraxial tip dimensional configurations and technological characteristics and standards.

The operational characteristics, when compared to the predicate device, are identical. The user connects the syringe via a standard slip tip or threaded luer lock, then manually advances or withdraws the plunger internal to the barrel to express or withdraw fluids. Fluids are measured via the printed external housing of the barrel; measurements are indicated in cc (milliliters). Operation is similar for most all piston syringes whether fitted with a threaded luer end, a slip-fit tip or neuraxial tip.

The subject device standard syringes are similar in materials and performance to the Sponsor's currently distributed standard syringes cleared in K103736. The technological characteristics of the subject device neuraxial syringes are consistent with ISO standard and are equivalent to the predicate device cleared in K170218.

Conclusion:
The MHC Standard and NRFit™ Tip Syringes are intended to inject fluids into or withdraw fluids from the body. The materials, intended use, technological and operational characteristics of the subject devices are substantially equivalent to the predicate Standard Syringes of K103736 and the neuraxial syringes cleared in K170218.