July 30, 2020

MY01, Inc.
Charles Allan
Chief Executive Officer
85 Rue Saint-Paul Ouest, Suite 200
Montreal, H2Y 3V4 Ca

Re: K193321
Trade/Device Name: MY01 Continuous Compartmental Pressure Monitor
Regulatory Class: Unclassified
Product Code: LXC
Dated: July 29, 2020
Received: July 30, 2020

Dear Charles Allan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi
Assistant Director
DHT6A: Division of Joints Arthroplasty
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K193321

Device Name
MY01 Continuous Compartmental Pressure Monitor

Indications for Use *(Describe)*
The MY01 Continuous Compartmental Pressure Monitor is intended for real-time and continuous measurement of compartmental pressures. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome.
The trend arrows provide a general pressure direction and are for informational purposes only. Do not rely upon the trend arrows for the diagnosis of compartment syndrome.

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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K193321

510(k) Summary for the MY01 Continuous Compartmental Pressure Monitor

In accordance with the requirements of 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness for the MY01 Continuous Compartmental Pressure Monitor.

A. SUBMITTERS INFORMATION

Submitted by: MY01, Inc.
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Montréal, Québec, H2Y 3V4, CANADA

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Regulatory Affairs and Compliance Officer
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Date Prepared: November 27, 2019

B. DEVICE INFORMATION

Registration Number: TBD
Device Trade Name: MY01 Continuous Compartmental Pressure Monitor
Device Common Name: Monitor, Pressure, Intracompartmental
Classification Name: Unclassified
Classification Code: LXC
Classification Panel: Orthopedic
Regulation Number: Pre-Amendment, Unclassified

C. PREDICATE DEVICE

K131966 Twin Star Extremity Compartment Monitor and Fluid Collection System (ECM-III)

D. DEVICE DESCRIPTION

The MY01 Continuous Compartmental Pressure Monitor (MY01 device) is a device for measuring real-time and continuous compartmental pressure. The measured compartmental pressures should always be used along with the current standard of care as an aid in the diagnosis of compartment syndrome.

The device is supplied sterile for single patient use and can be used up to a maximum of 18 hours, at which point a warning message is displayed cautioning the user. It contains two major components that are referred to as the Introducer (plastic housing and 17-gauge stainless-steel needle)

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and the Pressure Monitor. The Pressure Monitor consists of a capacitive Micro-Electro-Mechanical System (MEMS) pressure sensor, which allows for the measurement of intracompartmental pressure relative to a secondary atmospheric pressure sensor. It is embedded on a flexible PCB circuit, which extends via a lead-wire to a rigid PCB circuit within the Pressure Monitor. The Introducer allows for placement of the pressure sensor into muscle compartments. The Pressure Monitor continuously outputs pressure values on the LCD screen and can be attached on the patient's skin using the provided adhesive strip on the underside.

E. INTENDED USE/INDICATIONS FOR USE

The MY01 Continuous Compartmental Pressure Monitor is intended for real-time and continuous measurement of compartmental pressures. The measured compartmental pressures can be used along with the current standard of care as an aid in the diagnosis of compartment syndrome. The trend arrows provide a general pressure direction and are for informational purposes only. Do not rely upon the trend arrows for the diagnosis of compartment syndrome.

This intended use for the MY01 subject device is identical to the predicate device, with the exception of the latter's ability for fluid withdrawal for analysis. Since, this is an additional indication, it does not impact the intended use for continuous measurement of compartment pressures and thus, does not affect the safety and effectiveness of the subject device.

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The MY01 device has the similar intended use and equivalent indications for use as the predicate Twin Star device.

The devices have the following technological similarities:

- Use of continuously inserted measuring pressure sensor;
- Use of LCD display monitor to display pressure values in mmHg;
- Sterile and single use introducer mechanism;
- Use of stainless-steel needle or trocar as introducers;
- Similar insertion sites;
- Use of software to provide pressure readings;
- Use of external or built-in battery for power source.

The following technological differences exist between the subject and predicate device:

- The predicate device uses fiber optics to sense a change in pressure while the MY01 device measures a change in sensor capacitance, however both devices use established effective methods incorporating membranes to measure relative pressure;

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- The predicate device uses a porous catheter to host the pressure sensor while MY01 device uses a flexible printed circuit to host the pressure sensor
- The predicate device includes a reusable monitor, a sterile catheter for single-patient and a vacuum pump that may be connected to a fluid collection catheter, while the MY01 device supplied sterile for single-patient use and does not provide a means for fluid collection

The MY01 device is substantially equivalent to the Twin Star predicate device based on intended use and indications for use, method of use for measuring intracompartmental pressure, and compliance to FDA recognized safety and performance consensus standards. The differences in technological characteristics are not significant and do not raise additional questions of safety and effectiveness as it can be demonstrated by a review of predicate device characteristics, design and development standards, and non-clinical performance testing. The differences in materials and manufacturing processes have been successfully assessed for safety and effectiveness using the same industry testing methods for the subject device.

G. PERFORMANCE DATA

Systematic risk analysis was conducted in accordance with ISO 14971 and risks were mitigated as far as possible considering device sterility at the point of care, the biological safety of device materials, electrical safety and electromagnetic compatibility (EMC), hardware and software component specifications, and human factors for the intended use:

- Device sterility, shelf life, and packaging integrity to the point of use were validated according to FDA recognized industry standards and guidance documents.
- The biological safety of final finished, sterile device was evaluated in accordance with FDA guidance on the *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (2016), and the current FDA recognized standard ISO 10993-1, for externally communicating devices with limited contact duration (≤24 h).
- Electrical safety and performance requirements were assessed in compliance with the current FDA recognized standard IEC 60601-1 (Ed. 3.1). Both the subject device and Twin Star predicate device fall under similar degree of protection and mode of operation.
- EMC was assessed in compliance with the FDA recognized standard IEC 60601-1-2 (Ed. 4). Both the predicate and subject device were found to comply with the limits for a Group 1 Class B device according to this standard.
- Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (2005) for a 'moderate' level of concern.

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- Hardware and software device specifications were verified for conformity to design input requirements and were validated under simulated use conditions in accordance with FDA guidance *on Applying Human Factors and Usability Engineering to Medical Devices* (2016).

The MY01 device successfully met the criteria for safety of materials, maintenance of sterility and packaging integrity and ease of use of the device in a simulated use. Additionally, the results of successful verification and validation testing in compliance with current FDA recognized consensus standards and guidance provide a high level of assurance that the MY01 device fulfills design input requirements and established performance criteria and demonstrate the effectiveness of risk mitigations for the intended use. Thus, the performance testing for the subject device, using acceptable methods, ensures equivalent level of safety and effectiveness as the predicate device.

H. CONCLUSION

Both the predicate device and the MY01 Continuous Compartmental Pressure Monitor are intended for continuous measurement of intracompartmental pressures, the values of which can be used as an aid in diagnosis of compartment syndrome. There are only minor technological differences between the two devices. However, the similarities in function, purpose, display method of pressure values and the extensive performance testing for the subject device assure that the MY01 device is at least as safe and effective as the previously cleared predicate device. Thus, we believe the subject device (MY01 device) is substantially equivalent to the predicate (Twin Star) device.