May 24, 2022

MY01 Inc.
Anthony Sirgi
Director of Regulatory Affairs and Quality Assurance
400 De Maisonneuve Boulevard West, Suite 700
Montreal, Quebec H3A 1L4
Canada

Re: K220952
Trade/Device Name: MY01 Continuous Compartmental Pressure Monitor
Regulatory Class: Unclassified
Product Code: LXC
Dated: March 28, 2022
Received: April 1, 2022

Dear Anthony Sirgi:

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,

Limin Sun, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220952

Device Name
MY01 Continuous Compartmental Pressure Monitor

Indications for Use *(Describe)*
The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of the muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.

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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510(k) Summary

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.

807.92 (a)(1): SUBMITTERS INFORMATION

Submitted by:	MY01, Inc. 400 De Maisonneuve Boulevard West, Suite 700 Montréal, Québec, H3A 1L4 Canada
Contact Person:	Anthony Sirgi Director of Regulatory Affairs and Quality Assurance Address: MY01, Inc. 400 De Maisonneuve Boulevard West, Suite 700 Montréal, Québec, H3A 1L4 Canada Contact: Tel: +1 (514)-963-6027 Email: anthony.sirgi@my01.io
Date Prepared:	May 17, 2022
Establishment registration number:	3017398927
Owner Operator Number:	10061277

807.92 (a)(2): DEVICE INFORMATION

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

807.92 (a)(3): PREDICATE DEVICE

K210525: MY01 Continuous Compartmental Pressure Monitor

No reference devices were used in this submission.

807.92 (a)(4): DEVICE DESCRIPTION

The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.

The predicate MY01 Continuous Compartmental Pressure Monitor and MY01 Mobile Application are both cleared under traditional 510(k) **K210525.**

The MY01 Continuous Compartmental Pressure Monitor (MY01 device) is supplied sterile for single patient use and intended to be used for 18 hours, it contains two major components that are referred to as the Introducer (plastic housing and 17-gauge stainless-steel needle) and the Pressure Monitor. The Pressure Monitor consists of a capacitive Micro-Electro-Mechanical System (MEMS) pressure sensor, which allows for the measurement of intra-compartmental 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 to the patient's skin using the provided adhesive strip on the underside. MY01 device uses wireless communication over BLE to transmit muscle pressure data to a non-generic, compatible accessory, the MY01 Mobile Application, which is also developed by MY01, Inc..

The MY01 Mobile Application, cleared under **K210525** is intended for storing and displaying pressure values from the MY01 Continuous Compartmental Pressure Monitor. Authenticated users of the MY01 Mobile Application can securely connect to a MY01 device which enables the transmission of pressure data via an encrypted BLE link. The pressure values can be displayed as seen on the MY01 device or as a graph that is updated in real-time. The MY01 Mobile Application does not analyze or interpret pressure data on the MY01 device. The application is not able to control any functions or configuration of the MY01 device. The current pressure data measurement is displayed on the application and forwarded via an encrypted network link to a MY01 Application Server (cloud-based server) for data logging and archival purposes. The displayed and recorded pressure data is intended for informational purposes only and is not to be used for active-patient monitoring or diagnostic purposes.

Modification:
The modification that necessitated this submission entails the addition of a feature to the MY01 Mobile Application (cleared under **K210525**) that allows for calculation of perfusion pressure utilizing diastolic pressure manual entry by the physician. MY01, Inc. intends to release v1.16.0 of the MY01 Mobile Application with the modification described below.

The update to MY01 Mobile Application (v1.16.0) allows physicians to manually input a patient's diastolic pressure in the mobile application. As shown in **Figure 5.1**, the MY01 Mobile Application interface will now display diastolic pressure entered by the physician, in addition to the compartment pressure value received from the MY01 device. The data available is for informational purposes only and is not to be used for active-patient monitoring or diagnostic purposes, as indicated on the user interface, in the MY01 device and MY01 Mobile Application User Manuals. Both diastolic and compartment pressures are forwarded via an encrypted network link to the MY01 Application Server (back-end and cloud-based server) for data logging, archival and perfusion pressure calculation. Once the monitoring period is over, the physician can make a request to MY01 Inc. to retrieve the perfusion pressure log for a patient. MY01 Mobile Application and MY01 device User Manuals provide information for requesting perfusion pressure logs. Perfusion pressure is the difference between the diastolic pressure and muscle pressure. The calculation is made by MY01 Application Server using a simple subtraction algorithm:

Perfusion Pressure = (Diastolic Pressure - Muscle Pressure)

The perfusion pressure log can be exported from the MY01 Application Server in the format of a Comma Separated Value (.csv) file and will be sent to the user. The addition of the aforementioned feature does not alter, interpret or analyze the data presented on the MY01 device. The MY01 Mobile Application does not control the functions or parameters of the MY01 device in any way. The availability of perfusion pressure measurement offers valuable information to the users that can be used along with clinical assessment for retrospective analysis.

No change is made to the MY01 Continuous Compartmental Pressure Monitor device (introducer, pressure monitor or firmware) due to this modification in the MY01 Mobile Application. Hence, no technological differences exist between the subject and predicate devices except the described modification.

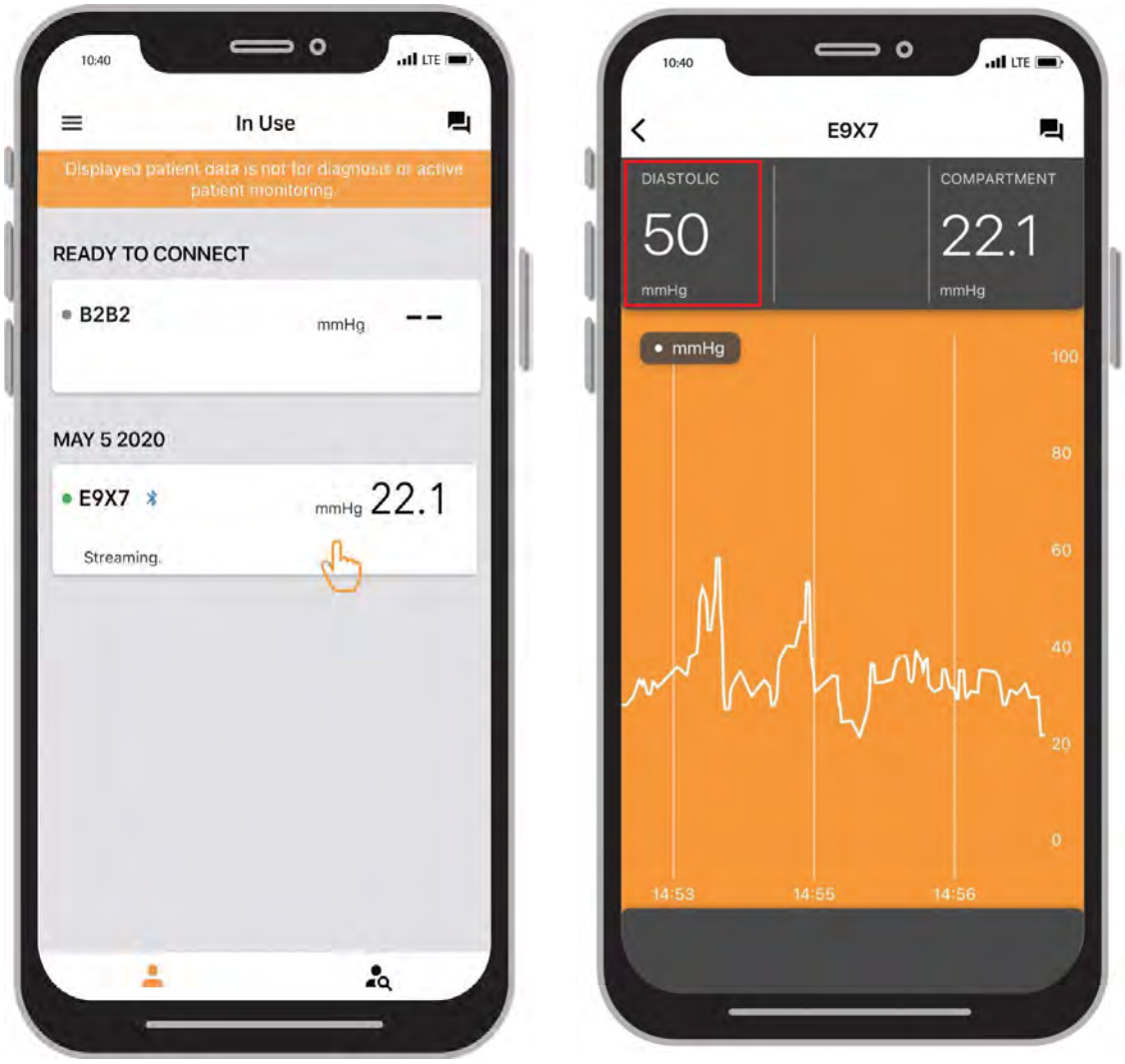

***Figure 5.1*:** User-interface change on the MY01 Mobile Application

807.92 (a)(5): INTENDED USE/ INDICATIONS FOR USE

The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of the muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.

The Indications for Use statement for the subject MY01 device is not identical to the predicate device, due to addition of diastolic pressure manual entry for perfusion pressure calculation, clarification of Acute and Chronic state of Compartment Syndrome, repositioned warning sentence from indication for use statement to relevant sections, and other clarifying minor changes to terminology. However, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for real-time and continuous monitoring of compartmental pressure, the values of which can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The additional feature does not alter, interpret or analyze data from the MY01 Continuous Compartmental Pressure Monitor, nor does it control the functions or parameters of the MY01 device in any way.

807.92 (a)(6): TECHNOLOGICAL SIMILARITIES AND DIFFERENCES TO THE PREDICATE

The subject MY01 device has the same intended use as its predicate. The technological characteristics of the subject MY01 Continuous Compartmental Pressure Monitor and predicate remain identical since no changes have been made to the MY01 device because of the modification to MY01 Mobile Application v1.16.0 (diastolic pressure entry). The subject MY01 device has a shelf-life of 12 months, different than that of the predicate device (6 months). The MY01 Mobile Application differs from the predicate due to addition of diastolic pressure manual entry feature.

The subject MY01 device is substantially equivalent to its predicate based on intended use, method of measuring intra-compartmental pressure, and compliance to FDA recognized safety and performance consensus standards.

807.92 (b)(1), (b)(3): PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing
Systematic risk analysis of the modified device was conducted in accordance with ISO 14971:2019. The following FDA recognized standards and FDA guidance were used to evaluate the safety and performance of the modified device and support substantial equivalence:

- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software -Software life cycle processes [FR Recognition Number: 13-79]
- Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005)

The subject MY01 device successfully PASSED all verification and validation testing. 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 an equivalent level of safety and effectiveness as the predicate device.

Packaging Validation

The shelf-life of MY01 Continuous Compartmental Pressure Monitor has been changed to 12 months following successful completion of packaging validation testing as per ISO 11607.

807.92 (b)(1), (b)(3): SUBSTANTIAL EQUIVALENCE CONCLUSION

The subject MY01 Continuous Compartmental Pressure Monitor (MY01 device) is substantially equivalent to the predicate device (**K210525**) based on identical intended use, technological characteristics, and compliance to FDA recognized safety and performance consensus standards. Except for the modifications described in this submission, the subject device is identical to the predicate device. The modification to MY01 Mobile Application does not raise additional questions of safety and effectiveness. Risk analysis, Functional and performance verification and validation testing with the added feature were carried out successfully to ensure the safety and performance of the MY01 Mobile Application for its intended use. Thus, the subject device is at least as safe and effective as the legally marketed predicate device.