April 22, 2021

MY01 Inc.
Anthony Sirgi
Regulatory Affairs and Compliance Officer
400 De Maisonneuve Boulevard West, Suite 700
Montreal, Quebec H3A 1LA
CANADA

Re: K210525
Trade/Device Name: MY01 Continuous Compartmental Pressure Monitor
Regulatory Class: Unclassified
Product Code: LXC
Dated: February 16, 2021
Received: February 23, 2021

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,

Vesa Vuniqi
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)*
K210525

Device Name
MY0l Continuous Compartmental Pressure Monitor

Indications for Use *(Describe)*
The MY0l 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 displayed are meant for qualitative purposes only and are not intended to have any clinical significance. The MY01 Mobile Application is an optional application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device. The data is for informational purposes only and is not intended to be used for diagnosis of any nature or active patient monitoring.

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.**

# 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.

**SUBMITTERS INFORMATION**

| | |
|---|---|
| **Submitted by:** | MY01, Inc.<br>400 De Maisonneuve Boulevard West, Suite 700<br>Montréal, Quebec, H3A 1L4<br>Canada |
| **Establishment Registration Number:** | 3017398927 |
| **Owner Operator Number:** | 10061277 |
| **Contact Person:** | Anthony Sirgi<br>Address: 400 De Maisonneuve Boulevard West, Suite 700<br>Montréal, Quebec, H3A 1L4<br>Canada<br>Regulatory Affairs and Compliance Officer<br>Tel: (514) 963-6027<br>Email: anthony.sirgi@my01.io |
| **Date Prepared:** | April 20, 2021 |

**DEVICE INFORMATION**

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

## PREDICATE DEVICE

**K202635** MY01 Continuous Compartmental Pressure Monitor

## 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 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 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.

MY01 device uses wireless communication over BLE to transmit data to an optional, non-generic compatible accessory mobile application, which is also developed by MY01 Inc. for data logging and archival purposes and both cleared under Traditional 510(k), K202635.

The MY01 Mobile Application cleared under K202635 is a Non-Device MDDS as per FDA guidance documents "Policy for Device Software Functions and Mobile Medical Applications" and "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices" (both issued on September 27, 2019) and is therefore not subject to FDA regulatory requirements applicable to devices.

**Table 1:** Accessories Marketed under MY01 Continuous Compartmental Pressure Monitor

| No. | Accessory | 510(k) Premarket Notification Number |
|---|---|---|
| 1 | MY01 Mobile Application | K202635 (with parent MY01 device) |

**Modification:**

The modification that necessitated this submission entails the addition of a graphing feature to the accessory MY01 Mobile Application cleared for the same manufacturer, MY01 Inc., under premarket notification K202635. The added graphing feature to the accessory MY01 Mobile Application is for informational purposes only and is not intended for active patient monitoring or diagnosis.

MY01 Inc. intends to release MY01 Mobile Application with an option to display the recorded pressure data either as displayed on the MY01 device itself or as a graph that is updated in real-time. This MY01 Mobile Application release shall replace the MY01 Mobile Application cleared under the predicate device (K202635). Authenticated users of the Mobile Application can

securely connect to a MY01 device which enables the transmission of pressure data via an encrypted BLE link. The current pressure data measurement is displayed on the application and forwarded via an encrypted network link to a cloud-based server (MY01 Application Server) for data logging and archival purposes. The optional graphical display option does not alter, interpret, or analyze the MY01 device data. The MY01 Mobile Application does not control the functions or parameters of the MY01 device in any way. The graphical display option offers physicians visual cues on sudden excursions in real-time. Such events may, for example, relate to the patient's physical movement, adjusting of bandages or cast around the limb rather than the clinical condition. The graph will therefore help physicians in taking note of such events (e.g. on patient records). The displayed and recorded graph is intended for informational purposes only and is not to be used for active-patient monitoring or diagnostic purposes, as indicated in the MY01 device and MY01 Mobile Application User Manuals. Therefore, the graphing feature does not alter the intended use of the MY01 device. Data collected from graph is archived on the same cloud database as the raw recorded pressure data and can be reviewed at a later time.

## 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 as an aid in the diagnosis of compartment syndrome. The trend arrows displayed are meant for qualitative purposes only and are not intended to have any clinical significance. The MY01 Mobile Application is an optional application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device. The data is for informational purposes only and is not intended to be used for diagnosis of any nature or active patient monitoring.

### Technological Similarities and Differences to the Predicate

The subject MY01 device has similar Intended Use/Indications for Use as the cleared predicate MY01 device (K202635). The only change to the Intended Use/Indications for Use of the subject MY01 device is the addition of the Intended Use/Indications for Use of the optional MY01 Mobile Application. This change in Intended Use/Indications for Use raises no additional questions of safety and effectiveness. The subject MY01 device has the same technical specifications as the predicate MY01 device with the exception of the graphical display feature added to the accessory MY01 Mobile Application.

## PERFORMANCE DATA

Systematic risk analysis of the modified device was conducted in accordance with ISO 14971:2007. The following FDA recognized standards and FDA guidance were used to evaluate the safety and performance of the modified device and support substantial equivalence:

- Software verification per IEC 62304:2006/AMD1:2015 Medical device software-Software life cycle processes-Amendment 1
- 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, demonstrating the effectiveness of risk mitigations and providing a high level of assurance that the subject MY01 device fulfills design input requirements and meets established performance criteria for the intended use.

**SUBSTANTIAL EQUIVALENCE CONCLUSION**

The subject MY01 device has similar Intended Use/Indications for Use as the cleared predicate MY01 device (K202635). The only change to the Intended Use/Indications for Use of the subject MY01 device is the addition of the Intended Use/Indications for Use of the optional MY01 Mobile Application. This change in Intended Use/Indications for Use raises no additional questions of safety and effectiveness. Additionally, the modified subject device uses the same fundamental technology, basic design and operating principle for its intended use and is manufactured and sterilized using the same materials and processes as the predicate device. Except for the modifications described in this submission, the subject device is identical to the predicate devices, and the performance data and risk analysis demonstrate that any differences between these devices do not raise new questions of safety and effectiveness and the subject device is at least as safe and effective as the legally marketed predicate device.