March 13, 2025

MY01 Inc.
Olivier Bataille
Chief Operating Officer
400 De Maisonneuve Boulevard West, Suite 700
Montreal, QC H3A 1L4
Canada

Re: K242997
Trade/Device Name: MY01 Continuous Compartmental Pressure Monitor
Regulatory Class: Unclassified
Product Code: LXC
Dated: September 26, 2024
Received: February 11, 2025

Dear Olivier Bataille:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Limin Sun, Ph.D.
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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K242997

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.**

MY01

# 510(k) Summary

The following information is submitted in accordance with the requirements of 21 CFR 807.92.

**Date Prepared:** February 10, 2025

### 807.92 (a)(1): SUBMITTER'S INFORMATION

| | |
|---|---|
| **Submitted by:** | MY01, Inc.<br>400 De Maisonneuve Boulevard West, Suite 700<br>Montréal, Québec, H3A 1L4<br>Canada |
| **Contact Person:** | Olivier Bataille<br>Chief Operating Officer<br>Tel: +1 (855) 799-6901<br>Email: olivier.bataille@my01.io |
| **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 Devices (OHT6) |
| **Regulation Number:** | Pre-Amendment, Unclassified |

### 807.92 (a)(3): PREDICATE DEVICE

MY01 Continuous Compartmental Pressure Monitor, K220952 (MY01, Inc.)

### 807.92 (a)(4): DEVICE DESCRIPTION

The MY01 Continuous Compartmental Pressure Monitor (the MY01 device) allows for continuous measurement and real-time display of muscle compartment pressure that is intended to be used as an aid in the diagnosis of Compartment Syndrome (Acute and Chronic).

The MY01 device is a single-use, sterile, prescription medical device. It consists of two major components: the Introducer (with a plastic housing and 17-gauge stainless-steel needle that allows for placement of a pressure sensor into muscle compartments) and the Pressure Monitor. The Pressure Monitor is a battery-powered, software/firmware controlled component that uses a capacitive Micro-Electro-Mechanical System (MEMS) sensor to measure muscle compartment pressure relative to atmospheric pressure obtained using a second MEMS sensor

embedded within the device enclosure. The embedded software/firmware system in the Pressure Monitor handles all processing functions of the MY01 device. Pressure measurements, user notifications, and device status information are displayed on the LCD screen of the Pressure Monitor and stored in non-volatile memory.

The MY01 device communicates securely via Bluetooth with the MY01 Mobile Application (the MY01 App) to transmit and display continuously in real time the measured muscle compartment pressure, user notifications and device status information. The muscle compartment pressure is displayed on the MY01 App along with the estimated muscle perfusion pressure that is derived using a manually entered diastolic pressure. The perfusion pressure is calculated using a simple subtraction: Muscle Perfusion Pressure = Diastolic Pressure - Muscle Compartment Pressure. The muscle compartment pressure is displayed as real-time numerical values and a continuously updated graph to visualize pressure trends over time. The muscle perfusion pressure is also displayed continuously with a dashed black line, indicating the estimated perfusion pressure based on the latest diastolic pressure entry. The time points of diastolic pressure entries are marked with solid black dots, indicating the calculated perfusion pressure at those specific times.

The MY01 App does not analyze or interpret pressure data and it does not control any function or the configuration of the MY01 device. The MY01 App is not intended for active patient monitoring.

Optionally, the MY01 App may connect via an encrypted Wi-Fi/Cellular network to the MY01 Application Server (a cloud-based server managed by MY01 Inc.) to transmit the recorded session and pressure data for off-line review, reporting and archival purposes. Registered clinicians using a MY01 device may review previously recorded session data on the MY01 App and may download this data from the cloud server as a comma separated value (.csv) file. The MY01 Application Server is a Non-Device MDDS; it does not modify the device data, does not control the functions or parameters of any medical device, and does not analyze or interpret the device data.

**Notable changes from the predicate device:**

The device modification that necessitated this 510(k) submission entails the calculation and continuous display of the estimated muscle perfusion pressure.

Additionally, the shelf life of the sterile MY01 Continuous Compartmental Pressure Monitor device (introducer and pressure monitor) has been extended to 24 months.

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

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 subject MY01 Continuous Compartmental Pressure Monitor has the same intended use and indications for use as the predicate device.

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

| Device Characteristic | Predicate Device (K220952) | Subject Device | Comparison |
|---|---|---|---|
| Manufacturer | MY01 Inc. | MY01 Inc. | Same |
| Device Trade Name | MY01 Continuous Compartmental Pressure Monitor | MY01 Continuous Compartmental Pressure Monitor | Same |
| Product Code | LXC – Monitor, Pressure, Intracompartmental | LXC – Monitor, Pressure, Intracompartmental | Same |
| Regulation | Pre-Amendment, Unclassified | Pre-Amendment, Unclassified | Same |
| 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 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. | Same |
| Prescription Use | Yes | Yes | Same |
| Target Patient Population | Patients susceptible to developing compartment syndrome | Patients susceptible to developing compartment syndrome | Same |
| Intended Anatomical Site | Extremities | Extremities | Same |
| Environment of Use | Healthcare environment | Healthcare environment | Same |
| Means of Accessing Anatomical Site to Measure Pressure | Introducer consisting of plastic housing with attached 17-gauge stainless-steel needle | Introducer consisting of plastic housing with attached 17-gauge stainless-steel needle | Same |
| Pressure sensing technology | Capacitive Micro-Electro-Mechanical Sensor (MEMS) | Capacitive Micro-Electro-Mechanical Sensor (MEMS) | Same |
| Compartmental Pressure Display | Handheld LCD with adhesive strip backing for optional attachment to patient's skin | Handheld LCD with adhesive strip backing for optional attachment to patient's skin | Same |
| Pressure Range | -99.9 to 99.9 mmHg | -99.9 to 99.9 mmHg | Same |

MY01

| Device Characteristic | Predicate Device (K220952) | Subject Device | Comparison |
|---|---|---|---|
| Sold Sterile | Yes | Yes | Same |
| Sterilization Method | Ethylene Oxide (EtO) | Ethylene Oxide (EtO) | Same |
| Shelf Life | 12 Months | 24 Months | Different. Validated as per ISO 11607-1:2019 |
| Maximum Intended Duration of Use | 18 hours | 18 hours | Same |
| Power Source | Two non-rechargeable and non-replaceable 3V batteries | Two non-rechargeable and non-replaceable 3V batteries | Same |
| IP Rating (Ingress Protection) | IP53 | IP52 | Different. The battery-powered Pressure Monitor is adequately protected in the intended use environment. |
| Wireless Connectivity | The monitor communicates securely via Bluetooth Low Energy (BLE) v4.2 with the MY01 Mobile Application | The monitor communicates securely via Bluetooth Low Energy (BLE) v4.2 with the MY01 Mobile Application | Same |
| EMC & Electrical Safety Standards | IEC 60601-1<br>IEC 60601-1-2<br>FCC Subpart 15C | IEC 60601-1<br>IEC 60601-1-2<br>FCC Subpart 15C | Same |
| Firmware | v1.7.0 | v1.8.0 | Different. Non-significant changes verified as per IEC 62304:2015. There is no impact on device function, safety or effectiveness. |
| MY01 Mobile Application | v1.16.0<br><br>iOS and Android Mobile device compatibility | v1.22.0<br><br>iOS and Android Mobile device compatibility | Different. The software has been updated with the notable functional changes listed below. It incudes technical changes for improved user experience and cybersecurity. The changes do not adversely affect device function, safety or effectiveness. |
| | Does not provide a diagnosis; labelled not to be used for active patient monitoring | Does not provide a diagnosis; labelled not to be used for active patient monitoring | Same |
| | Display of device-measured muscle compartment pressure (numerical value & continuously updated graph) | Display of device-measured muscle compartment pressure (numerical value & continuously updated graph) | Same |
| | Manual entry and display of diastolic blood pressure (range: 0-200 mmHg) | Manual entry and display of diastolic blood pressure (range: 10-200 mmHg) | Same, with minor (not clinically significant) change in the acceptable input range. |

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| Device Characteristic | Predicate Device (K220952) | Subject Device | Comparison |
|---|---|---|---|
| | -- | Option to set the diastolic blood pressure value for multiple MY01 devices used concurrently on the same patient | Different. Functionality added to promote consistency of manual entries across multiple recording devices. No adverse impact on device safety and effectiveness. |
| | -- | Option to set a periodic reminder to update the diastolic blood pressure value | Different. Functionality added to promote the use of the most recent diastolic blood pressure measurement in calculating and displaying perfusion pressure. No adverse impact on device safety and effectiveness. |
| | -- | Option to edit previously entered diastolic blood pressure values | Different. Functionality added to mitigate for use error and ensure the displayed perfusion pressure trend reflects actual clinical diastolic pressure measurement. No adverse impact on device safety and effectiveness. |
| | Perfusion pressure is calculated and available off-line on the connected MY01 Application Server (a cloud-based server managed by MY01 Inc. as a Non-Device MDDS). There is no display of perfusion pressure on the MY01 Mobile Application | Perfusion pressure is calculated using manually entered diastolic pressure readings. The estimated perfusion pressure is continuously displayed together with the device-measured muscle compartment pressure (numerical value & continuously updated graph) along with the time and value of the latest diastolic pressure reading. | Different. Functionality added to display the value and trend of a clinically useful parameter that would be otherwise estimated by the attending clinicians. Clinicians can independently validate the results based on displayed values on the Mobile Application and the device itself. No adverse impact on device safety and effectiveness. |
| | Access to cloud server via encrypted Wi-Fi/Cellular network connection for off-line review, reporting and archival purposes (Registration with MY01 Inc. required) | Access to cloud server via encrypted Wi-Fi/Cellular network connection for off-line review, reporting and archival purpose (Registration with MY01 Inc. required) | Same |

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

Software system verification testing at the unit-level and functional, system-level (end-to-end) testing of the modified device were successfully conducted in accordance with the IEC 62304:2015 consensus standard, design control requirements per Quality System Regulation (21 CFR 820), and FDA guidance following systematic risk assessment in accordance with ISO 14971:2019. The modified software system was also assessed for cybersecurity risks, and it was subject to vulnerability scanning in accordance with FDA guidance.

The extended shelf life of the sterile device was validated by successful completion of sterile package integrity and performance testing using real-time aged devices in accordance with ISO 11607-1:2019.

Clinical testing was not required to demonstrate substantial equivalence for this device type.

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

The software and labeling changes to the MY01 Continuous Compartmental Pressure Monitor device do not raise new questions of safety and effectiveness. The evidence submitted in this 510(k) Notification supports a finding of substantial equivalence, as it demonstrates that the subject device fulfills its design and risk management requirements, it is as safe and as effective for its intended use, and it performs as well as or better than the legally marketed predicate device.