MY01, Inc.
Anthony Sirgi
Regulatory Affairs and Compliance Officer
400 De Maisonneuve Boulevard West, Suite 700
Montreal, Quebec H3A 1L4
Canada

December 10, 2020

Re: K202635
Trade/Device Name: MY01 Continuous Compartmental Pressure Monitor
Regulatory Class: Unclassified
Product Code: LXC
Dated: October 21, 2020
Received: October 23, 2020

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)*
K202635

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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.

SUBMITTERS INFORMATION

Submitted by:	MY01, Inc. 400 De Maisonneuve Boulevard West, Suite 700 Montréal, Quebec, H3A 1L4 Canada
Establishment Registration Number:	3017398927
Owner Operator Number:	10061277
Contact Person:	Anthony Sirgi Address: 400 De Maisonneuve Boulevard West, Suite 700 Montréal, Quebec, H3A 1L4 Canada Regulatory Affairs and Compliance Officer Tel: (514) 963-6027 Email: anthony.sirgi@my01.io
Date Prepared:	December 08, 2020

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

K193321 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.

Modification: The purpose of this submission is an enhancement of the device functionality to include wireless communication over Bluetooth Low Energy (BLE) to transmit data to a compatible mobile application for data logging and archival purposes.

The MY01 mobile application does not analyze of interpret recorded pressure data. It is not intended to aid in diagnosis or monitoring. The application is not able to control any functions or configuration parameters of the MY01 device. Authenticated users of the mobile application can securely connect to a MY01 device and enable 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.

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.

Technological Similarities and Differences to the Predicate

The subject MY01 device has the same intended use and indications for use as the cleared predicate MY01 device (**K193321**).

The subject MY01 device has the same technical specifications as the predicate MY01 device with the exception of the enabled BLE wireless connectivity.

PERFORMANCE DATA

Systematic risk analysis of the modified device was conducted in accordance with ISO 14971 considering possible cybersecurity vulnerabilities and interoperability characteristics introduced by the BLE connectivity. The following established test methods, FDA recognized standards and FDA guidance were used to evaluate the safety and performance of the modified device and support substantial equivalence:

- Electrical Safety per IEC 60601-1-1
- EMC emissions per IEC 60601-1-2/CISPR 11 and 21 CFR 47 Part 15
- EMC Immunity per IEC 60601-1-2
- Software verification per IEC 62304
- Cybersecurity assessment per FDA guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.
- Interoperability assessment per FDA guidance: Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices.
- Radio Frequency Wireless Technology in Medical Devices – Guidance for Industry and FDA Staff.

The subject MY01 device with BLE wireless connectivity successfully PASSED all verification and validation testing, demonstrating the effectiveness of risk mitigations and providing a high level of assurance that the MY01 device fulfills design input requirements and meets established performance criteria for the intended use.

SUBSTANTIAL EQUIVALENCE CONCLUSION

The subject MY01 device has the same intended use and indications for use as the predicate device. 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.