April 4, 2024

Peleton Surgical
Andy Bala
Chief Executive Officer
1435 North Hayden Road
Suite 100
Scottsdale, Arizona 85257

Re: K240071
Trade/Device Name: Peleton Universal Single Use Power System and Attachments
Regulation Number: 21 CFR 878.4820
Regulation Name: Surgical Instrument Motors And Accessories/Attachments
Regulatory Class: Class I
Product Code: SAM
Dated: January 8, 2024
Received: January 10, 2024

Dear Andy Bala:

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.

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)*

K240071

Device Name

Peleton Universal Single Use Power System and Attachments

Indications for Use *(Describe)*

The Peleton Surgical Single Use Power Tool System is a battery driven tool system for use in Trauma, Orthopaedic and Cardio related Surgical Procedures involving drilling, reaming, pin & wire placement and cutting of bone and hard tissue.

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) #: K240071

510(k) Summary

Prepared on: 2024-04-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Peleton Surgical
Applicant Address	1435 North Hayden Road Suite 100 Scottsdale AZ 85257 United States
Applicant Contact Telephone	6302352227
Applicant Contact	Mr. Andy Bala
Applicant Contact Email	abala@peletonsurgical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Peleton Universal Single Use Power System and Attachments (PEL-5000)
Common Name	Battery-powered instruments charged through sterile barriers
Classification Name	Instrument, Surgical, Orthopedic, Dc-Powered Motor And Accessory/ Attachment
Regulation Number	878.4820
Product Code(s)	SAM

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K112599	Insurgical Single Use Power Equipment	KIJ
K972367	STRYKER SYSTEM 4000 HEAVY DUTY BATTERY POWERED	KIJ

Device Description Summary

21 CFR 807.92(a)(4)

The Peleton Surgical Universal Power System is a battery powered tool for use in cardio-ortho related surgical procedures and is designed for the efficient cutting of bone and hard tissue. Due to the sterile barrier charging, the device is readily charged and available for immediate use in the surgical setting. The Peleton Surgical Universal Power System's lithium-ion polymer battery is always fully charged with more power than is needed for any surgery. Surgical attachments are easily interchangeable and cover every aspect of large bone surgical procedures, including drilling, cutting reaming, sawing and surgical pin insertion and removal etc.

The Peleton Surgical Universal Power System is packaged in a double sterile barrier packaging system that includes internal and external electrical charging port features. This double sterile barrier packaging system consists of the device and its components being sealed inside an inner tray with a charging cable connecting the device and the inner tray charging port. The sealed inner tray is then sealed inside an outer tray with a charging cable connecting the inner tray charging port to the outer tray charging port. The charging port includes various components to ensure a tight seal that maintains the proper sterile barrier.

The Peleton Surgical Universal Power System includes a variety of metallic attachments (ASTM F899) that are used in clinical procedures. The system is compatible with a Sternum Saw, Reciprocating Saw, Oscillating Saw, Keyless Jacobs Chuck, Multi- Fit Hudson/Trinkle Reamer, Cannulated Pin and Wire Driver and Quick Release Drill Chuck. Each attachment is compatible with universal saws, drill bits and reamers from manufacturers of orthopedic accessories.

The single use Peleton Surgical Universal Power System was designed to instantly be ready to be delivered to the surgical field, reducing operating room time, eliminating the need for multiple batteries/changes on extended cases, eliminating the risk of potential bioburden

from improper cleaning from previous cases and reducing the amount of time needed to properly clean and re-sterilize the reusable system.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Peleton Surgical Single Use Power Tool System is a battery driven tool system for use in Trauma, Orthopaedic and Cardio related Surgical Procedures involving drilling, reaming, pin & wire placement and cutting of bone and hard tissue.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Indications for Use Comparison
The subject and predicate devices are intended to cut bone/prepare bone and to place screws, pins and wires and therefore have the same intended use.

Technological Comparison 21 CFR 807.92(a)(6)

Technological Comparison
The design, materials, and intended use of the Peleton Surgical Universal Power System are equivalent to the predicate device. Peleton Surgical Universal Power System and the predicate devices both contain an assortment of metallic attachments that are used for cutting bone and or placing pins, wires and screws. The subject device differs from the predicates because it includes additional technology that allows the driver to maintain sterility while being charged through the sterile barrier by directly connecting to a charging port integrated into the custom packaging tray.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non Clinical and/or Clinical Tests Summary and Conclusions
The Peleton Surgical Universal Power System was subjected to worst case usability testing to demonstrate successful function and performance. Additionally, testing on the battery safety and performance was also completed.

Testing that was completed includes:
1. Verification Testing
a. Visual Inspection
b. Dimensional Inspection
c. Operating frequency and stability
d. Temperature Monitoring

2. Corrosion Testing (ASTM F1089-18)
3. Attachment compatibility and simulated use testing (50 PCF bone foam substrate per ASTM F1839-08) including reaming, drilling, pin driving, sawing.
4. Tensile, Flexural and Torsional testing
5. Risk assessment, Battery basic safety testing and battery performance testing (Verification Testing and ST/SG/AC.10/11/Rev.6)
6. Packaging validation testing including assessment of all package seals, including the charging port. Simulated distribution and accelerated aging were performed to evaluate seal strength and integrity (visual inspection, peel strength testing, dye penetration testing). Dye penetration performance was confirmed for the subject device and packaging by comparison to a positive control (improperly assembled charging port). All testing was completed per applicable standards - ISO11607-1 and ISO11607-2
7. EMC testing per IEC 60601-1-2
8. Biocompatibility testing per ISO 10993 including cytotoxicity testing, sensitization testing, irritation testing, acute systemic toxicity testing, and material mediated pyrogenicity testing.

Conclusions
Based on the intended use, indications for use, technological characteristics, and performance
data, the subject Peleton Surgical Universal Power System is as safe and as effective and concluded to be substantially equivalent to the applicable predicate devices.