May 24, 2026

Parallel Robotics, LLC
Russell Jahnke
Quality Manager
3810 Packard St., Suite 100a
Ann Arbor, Michigan 48108

Re: K260183
Trade/Device Name: MediBot Needle Driver Uno
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 27, 2026
Received: April 28, 2026

Dear Russell Jahnke:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.05.24 10:42:12 -04'00'

Colin K. Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K260183

Device Name
MediBot Needle Driver Uno

Indications for Use *(Describe)*
The MediBot Needle Driver Uno medical device is intended to assist in accurate control of its needle holder instrument for endoscopic suturing during laparoscopic or abdominal minimally invasive surgical procedures. It is intended to be used by trained physicians in an operating room environment in accordance with its Instructions For Use.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K260183

510(k) SUMMARY

This 510(k) Summary of Safety and Effectiveness Information is submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared: January 21, 2026

Submitter:
Parallel Robotics, LLC
3810 Packard St., Suite 100A
Ann Arbor, MI 48108, USA

Contact Person:
Russell Jahnke
Quality Manager
Phone: (734) 680-4409
Email: Russell@parallelbot.com

DEVICE NAME AND CLASSIFICATION

Trade Name: MediBot Needle Driver Uno
510(k) Number: K260183
Classification Name: Laparoscope, General & Plastic Surgery
Classification Panel: General & Plastic Surgery
Classification Regulation: 21 CFR 876.1500
Device Class: Class II
Product Code: GCJ

PREDICATE DEVICE

Trade Name: HX Device
510(k) Number: K173919
Manufacturer: Human Extensions Ltd.
Classification Name: Laparoscope, General & Plastic Surgery
Classification Panel: General & Plastic Surgery
Classification Regulation: 21 CFR 876.1500
Device Class: Class II
Product Code: GCJ

Device Description:

The MediBot Needle Driver Uno is a single-use medical device that enables the surgeon to perform intracorporeal suturing and knot tying during laparoscopic or abdominal minimally invasive surgical procedures. The MediBot Needle Driver Uno consists of three elements: (a) the Uno Device, (b) Uno Cable, and (c) Uno Control Box . The Uno Device is connected to the Uno Control Box via the Uno Cable, which transmits electrical power and data to and from the Uno Device and Uno Control Box. The Uno Control Box (with onboard software/firmware) provides all electrical power and computation that is required for the Uno Device to operate.

During use, the user holds the Handle of the Uno Device , and provides articulation input by articulating their hand about their wrist. This articulation input leads to articulation of the needle holder instrument Jaws (i.e. End Effector), located at the distal end of the Uno Device. In addition to articulation, the user is also able to roll the Jaws of the Uno Device by turning the Roll Dial at the Handle. Finally, the user can open and close the Jaws by squeezing the Trigger at the Handle. The opening and closing of the Jaws enables grasping or holding of needles and sutures. A combination of articulation, roll, and opening/closing of the Jaws enables the user to perform intracorporeal suturing.

The Uno Device is an integral assembly that consists of a Hand-piece portion and an Instrument portion. There is no separation or connect/disconnect interface between the Hand-piece portion and Instrument portion of the Uno Device. This Hand piece portion and Instrument portion are equivalent to the HX Handpiece and HX Instrument (our chosen predicate). Additional details are provided in the Substantial Equivalence Comparison document.

Indications for Use:

The MediBot Needle Driver Uno medical device is intended to assist in accurate control of its needle holder instrument for endoscopic suturing during laparoscopic or abdominal minimally invasive surgical procedures. It is intended to be used by trained physicians in an operating room environment in accordance with its Instructions For Use.

Contraindications:

- Where laparoscopic surgery or abdominal minimally invasive surgery is contraindicated.

Technology Comparison and Substantial Equivalence:

The chosen predicate device is the Human Extensions HandX Device (K173919).

The MediBot Needle Driver Uno and the predicate HandX Device (with Needle Driver HX Instrument) have the same intended use (for suturing), indications for use, operating environment, and operating mode. Both devices are hand-held laparoscopic surgical instruments intended to assist surgeons in performing endoscopic suturing and knot tying during minimally invasive surgical procedures. Both devices are controlled by the surgeon at the patient bed-side in the operating room.

The MediBot Needle Driver Uno and the predicate device are both classified under 21 CFR 876.1500, product code GCJ, and are intended for use by trained physicians in an operating room environment.

Technological similarities between the subject and predicate devices include:

- Hand-held laparoscopic/endoscopic needle driver design
- Articulating distal end effector for intracorporeal suturing
- Jaw opening and closing functionality for needle and suture manipulation
- User control of articulation via inputs provided by the user's hand
- Used during minimally invasive surgical procedures such as laparoscopy
- Electrical and software-controlled operation

Technological differences between the subject and predicate devices include device-specific implementation details related to design, ergonomics, physical configuration, software architecture, and component integration. These differences do not alter the intended use, operating principles, or fundamental mechanism of action of the device.

Device performance testing was primarily evaluated through non-clinical testing and the test results demonstrate that any technological differences do not adversely affect device safety or effectiveness.

A summary of the substantial equivalence comparison between the MediBot Needle Driver Uno and the predicate device is provided below:

- Indications for Use – Equivalent
- Intended Use – Equivalent
- Principle of Operation (End Effector Articulation and Insertion Method) – Equivalent
- Surgeon hand-held at patient bedside – Equivalent
- Operating Environment – Equivalent
- Performance Testing – Equivalent
- Software and Cybersecurity – Equivalent
- Applicable Regulations, FDA Guidance, Special Controls, and Recognized Consensus Standards – Equivalent

Performance Testing

Non-clinical performance testing was conducted to support the substantial equivalence of the MediBot Needle Driver Uno to the predicate device and to demonstrate that the device performs as intended.

Testing included verification and validation activities associated with mechanical performance, functional performance, electrical safety, electromagnetic compatibility (EMC), software verification and validation, usability/human factors considerations, biocompatibility, sterilization, packaging, and shelf-life, as applicable to the device design and intended use.

Electrical safety and electromagnetic compatibility testing were conducted in accordance with applicable recognized consensus standards for medical electrical equipment, including IEC 60601-1 and IEC 60601-1-2, as applicable.

Software verification and validation activities were conducted consistent with FDA guidance for the content of premarket submissions for software contained in medical devices. Cybersecurity documentation and risk management activities were performed consistent with applicable FDA cybersecurity guidance.

Biocompatibility evaluation of patient-contacting materials was conducted consistent with ISO 10993 standards appropriate for the nature and duration of device contact.

Cleaning, Sterilization, and packaging validation testing were conducted using recognized consensus standards applicable to sterile, single-use medical devices.

Mechanical and functional performance testing demonstrated that the device performs as intended for laparoscopic suturing and needle manipulation functions. Testing confirmed acceptable articulation, jaw actuation, rotational control, and operational reliability under simulated use conditions.

All testing results met predetermined acceptance criteria and support the conclusion that the MediBot Needle Driver Uno is as safe and effective as the predicate device.

Conclusion

Based on the indications for use, technological characteristics, and results of the non-clinical performance testing, the MediBot Needle Driver Uno has been demonstrated to be substantially equivalent to the predicate HandX Device (K173919) as a needle driver.

The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness. Performance testing demonstrated that the subject device performs as intended and supports a determination of substantial equivalence in accordance with the requirements of 21 CFR 807.92(b)(3).