ROPCA ApS
Trine Winther
Head of Quality
Cortex Park 26 E
Odense M, 5230
Denmark

June 18, 2026

Re: K260190
Trade/Device Name: Arthur
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: May 15, 2026
Received: May 15, 2026

Dear Trine Winther:

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.06.18 13:00:20 -04'00' For

Yanna Kang, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260190

Please provide the device trade name(s).

ARTHUR

Please provide your Indications for Use below.

ARTHUR by ROPCA is intended to hold an external ultrasound transducer of cleared ultrasound equipment for automatic image capturing of finger and wrist joints.
ARTHUR is indicated for adult patients, that are under investigation or monitoring of musculoskeletal diseases.
The system shall be used in a professional healthcare facility environment.
ARTHURs mode of operation is to use B-mode (2D), Color Doppler and/or Power Doppler mode on connected ultrasound machines.
The clinical application is musculoskeletal ultrasound of the hand and wrist joints.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K260190

510(k) Summary

Prepared on: 2026-06-18

Contact Details

K260190

21 CFR 807.92(a)(1)

Applicant Name	ROPCA ApS
Applicant Address	Cortex Park 26 E Odense M 5230 Denmark
Applicant Contact Telephone	+45 22 53 22 07
Applicant Contact	Ms. Trine Winther
Applicant Contact Email	tw@ropca.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ARTHUR
Common Name	Ultrasonic pulsed echo imaging system
Classification Name	System, Imaging, Pulsed Echo, Ultrasonic
Regulation Number	892.1560, 892.1570, 892.1550, 892.2050
Product Code(s)	IYO, ITX, IYN, QIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K161354	MELODY, Remote Control System for Ultrasound Probe	IYO
K080555	Sofia Automated Tomographic Ultrasound (ATUS)	ITX

Device Description Summary

21 CFR 807.92(a)(4)

ARTHUR stands for ARTHritis Ultrasound Robot and is an accessory to already verified and FDA-cleared off the shelf ultrasound machines.

Upon connection with the ultrasound unit, ARTHUR can automatic capture ultrasound images of various joints of the fingers, hands, and wrists that can be utilized for medical review. The patient is supervised by a healthcare professional to follow the instructions from ARTHUR.

The main interface to the platform is an intuitive touchscreen that will guide the patient user through the stages of the examination process, supervised by a healthcare professional(e.g., hand placement, gel application). Through advanced camera technology, ARTHUR automatically detects the patient's hands - identifying their individual hand joints. Once proper hand placement is identified, the robotic arm moves an attached ultrasound probe to each individually selected joint, scanning them thoroughly while ensuring safe and proper contact between the patient and probe. During the scanning procedure, ARTHUR communicates with the ultrasound machine, simultaneously changing modes between greyscale and Doppler images. One grayscale image and one doppler video for each joint is saved on the platform for the clinician to review and use as assistance input for diagnosis and monitoring of musculoskeletal diseases.

ARTHUR is intended for use on adult patients, that are under clinical investigation for, or monitoring of, musculoskeletal diseases and operated/supervised by trained healthcare professionals. The intended environment of the device are healthcare facilities, as a healthcare professional is required.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

ARTHUR by ROPCA is intended to hold an external ultrasound transducer of cleared ultrasound equipment for automatic image capturing of finger and wrist joints.
ARTHUR is indicated for adult patients, that are under investigation or monitoring of musculoskeletal diseases.
The system shall be used in a professional healthcare facility environment.
ARTHURs mode of operation is to use B-mode (2D), Color Doppler and/or Power Doppler mode on connected ultrasound machines.
The clinical application is musculoskeletal ultrasound of the hand and wrist joints.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device are similar to the predicate device's indications for use as both devices are indicated to hold an already cleared third-party ultrasound probe by a software controlled robotic arm to perform an ultrasound scan.

The difference lies in how the software controlled robotic arm is operated. The predicate device is operated remotely by the sonographer with support of an on-site assistant, and the subject device's ultrasound image collection operated by software algorithms including artificial intelligence and is also supported by an on-site assistant. However, this difference has no influence on safety and performance, which is also supported by the reference device, as it also performs a fully automatic scan. Thus, the indications can be considered equivalent to the predicate as the artificial intelligence memes human behavior. Another difference lies in anatomical location, that also does not raise any new safety or performance issues, since both the subject and predicate device are accessories to already cleared ultrasound devices. Therefore, the intended anatomical sites, or any limitations thereon, are determined by the ultrasound device and its probes.

Technological Comparison

21 CFR 807.92(a)(6)

The general technological characteristics of the subject device and the predicate device are substantial equivalent, as both devices use software-controlled robotic arms to hold cleared third-party ultrasound probes for ultrasound scans. The primary technological difference between the two devices lies in the method of operation of the software-controlled robotic arm. The predicate device is operated remotely by a sonographer with assistance from an on-site operator, whereas the subject device operates fully automated by software algorithms that control probe positioning and ultrasound image acquisition supported by an on-site assistant. Hereby, the subject device's software uses algorithms to detect joint positions and control the robotic movements of the ultrasound probe, followed by a real-time analysis of the acquired ultrasound images, which enables the system to automatically identify and store the optimal ultrasound image of each joint. Both the joint position detection and the ultrasound image evaluation algorithms are based on artificially developed models that are fixed and non-adaptive during production. As the models are static, performance verification and validation are feasible and controlled. Therefore automatic movement of the ultrasound probe is comparable to the reference device. The ultrasound images will in the following treatment be review and used for clinical assessment.

Despite the difference in automation level, the technological characteristics do not raise new or different questions of safety or effectiveness, as the subject device is designed with Class C software in accordance with IEC 62304 and incorporates safety features including collision detection and a kinematic control system that limits the maximum applied force to 50 N and a force of 10N in normal use. The normal force is similar to the predicate device of 20 N. The differences are due to different anatomical structures and required pressure due to image quality. Despite this, there are no safety concerns, since this force limit is significantly below the thresholds recommended in ISO 15066 for human-robot interaction.

In addition, the device is equipped with different safety controls as an emergency button to stop the robotic arm movement abruptly or a mechanical release mechanism for the ultrasound probe to allow immediate disengagement from the patient in worst-case scenarios. The mechanical design, together with the software safety configuration, minimizes the risk of injury, trapping, or unintended contact during operation.

Based on the same intended use and the controlled differences in technological characteristics, the subject device is substantially equivalent to the predicate device. Performance data in support of the substantial equivalence determination e.g., biocompatibility testing in accordance to ISO 10993-1, electrical safety and electromagnetic compatibility according to IEC 60601-1 and IEC 60601-1-2 and other verification and validation testing is provided.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

ARTHUR by ROPCA is an accessory to a verified ultrasound machine(s) and provides an automatic way to capture ultrasound images of wrist and finger joints. According to the market analysis included in this evaluation, ARTHUR is a new solution for a growing market since it automates an already used and proven clinical method. The state of the art investigation also showed a clear indication of ultrasound being the preferred and dominant imaging modality currently available for early diagnosis and disease monitoring in possible musculoskeletal diseases.

Based on the risk management process, the residual risk and risk benefit analysis finds that ARTHUR does not expose the patient to any unacceptable risk. It showed an overall low residual risk for ARTHUR to capture images of insufficient quality or no images at all. However, this is of no hazard related consequence to the patient, thus this risk is mitigated by the doctor. The risk for the doctor is to revert to manually scanning the patient as it is done currently or use joint palpation. There is no risk related to the outcome of the treatment for the patients by introducing ARTHUR in the process.

The performance study and the usability study showed that ARTHUR was safe to use. Both the clinical personnel and the patients were able to understand the instructions and to complete the tests with few non-hazardous situations.

The performance studies showed conformity with the clinical benefit. Furthermore, ARTHUR by ROPCA conforms with the criteria for performance and benefit risk, and the literature investigated did not contradict the essential performance requirement. Based on the statistical analysis we have provided evidence that "ARTHUR shall succeed in scanning at least 85% on average of MCP 1-5, PIP 1-5, wrist RC-IC and DIP 1-4 per hand." thereby it can be claimed "ARTHUR by ROPCA automatically captures standardised ultrasound images of the hands for clinical use."

The Post-Market Surveillance (PMS) activities from EU market has not shown any changes to the conclusions from the initial release of this clinical evaluation and will be continued as defined in the PMS plan and ROPCA will continuously collect performance, safety and usability data which will be processed and used to ensure continued service and performance monitoring.

An additional Usability and performance study conducted at a clinic in USA was performed and has showed good results whereas all criteria and the clinical claim are fulfilled.

ARTHUR is a low-risk medical device incorporating multiple safety features, including software-based safety controls and a mechanical release mechanism for the third-party, FDA-cleared ultrasound probe. These safety features are designed to minimize the risk of injury during operation.

ARTHUR automatically acquires ultrasound images intended to support the diagnosis and monitoring of musculoskeletal diseases. The device does not provide diagnostic decisions; all acquired ultrasound images are intended to be reviewed and interpreted by qualified clinical professionals.

Performance testing demonstrates that ARTHUR successfully acquires diagnostically usable ultrasound images for at least 85% of targeted joints. Based on the intended use, technological characteristics, safety controls, and performance data provided in this submission, ARTHUR does not raise new or different questions of safety or effectiveness compared to the predicate device and is therefore substantially equivalent.