July 24, 2026

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

Re: K260192
Trade/Device Name: Diana
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 16, 2026
Received: June 16, 2026

Dear Trine Straarup 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,

Jessica Lamb, Ph.D.
Assistant Director, Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
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.	K260192

Please provide the device trade name(s).

DIANA

Please provide your Indications for Use below.

DIANA is intended for use in patients undergoing ultrasound examination of the hand and wrist joints. The device automatically analyzes musculoskeletal structures on pre-captured ultrasound images and provides decision support for identification of Synovial hypertrophy, Doppler activity, and Osteophytes presence/ absence. The user of the decision support shall be a healthcare professional trained and qualified in musculoskeletal (MSK) ultrasound. DIANA is limited to use with the system ARTHUR which performs automatic acquisition of ultrasound images.

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) #: K260192

510(k) Summary

Prepared on: 2026-07-24

Contact Details

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 Straarup Winther
Applicant Contact Email	tw@ropca.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DIANA
Common Name	DIANA
Classification Name	Medical Image Management and Processing System
Regulation Number	892.2050
Product Code(s)	QIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222406	Clarius AI	QIH

Device Description Summary

21 CFR 807.92(a)(4)

DIANA stands for Diagnosis Aid Network for Arthritis and is a software medical device, based on neural networks used for musculoskeletal ultrasound image analysis, that classifies and segments anatomical features, contributing to the diagnosis and monitoring of musculoskeletal diseases with a binary score(presence/absence). DIANA is a decision support tool for evaluating and monitoring the possible disease within anatomical joints based upon the ultrasound images of hand and wrist joints captured by ARTHUR. DIANA provides clinical decision support based upon the following parameters: Synovial hypertrophy, Doppler activity, and Osteophytes presence. DIANA is intended for adult patient utilization who are under clinical investigation, or monitoring of, musculoskeletal diseases and is intended to be utilized by trained healthcare professionals with experience in musculoskeletal diseases and the Global EULAR-OMERACT scoring system.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

DIANA is intended for use in patients undergoing ultrasound examination of the hand and wrist joints. The device automatically analyzes musculoskeletal structures on pre-captured ultrasound images and provides decision support for identification of Synovial hypertrophy, Doppler activity, and Osteophytes presence/absence. The user of the decision support shall be a healthcare professional trained and qualified in musculoskeletal (MSK) ultrasound. DIANA is limited to use with the system ARTHUR which performs automatic acquisition of ultrasound images.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has the same intended use as the predicate device. Both devices are intended to assist healthcare professionals trained in musculoskeletal (MSK) ultrasound, by preforming non-invasive processing of musculoskeletal ultrasound images, using segmentation of anatomical structures utilizing artificial intelligence algorithms. Both devices provide information to support clinical assessment and are not intended to replace clinical judgment.

The subject device is intended for use with ultrasound images of the hand and wrist, whereas the predicate device is intended for use with ultrasound images of the foot. This difference in anatomical site does not raise different questions of safety or effectiveness because both devices analyze musculoskeletal ultrasound images with comparable imaging characteristics using the same technological approach. Both anatomical regions comprise bones, tendons, synovium, and other soft tissues that can be reliably visualized and assessed using musculoskeletal ultrasound.

The subject device and the predicate device utilize non-adaptive (locked) artificial intelligence image segmentation algorithms to identify and segment anatomical structures in pre-captured ultrasound images. The generated segmentations are displayed to the user as overlays on the original ultrasound images to support image interpretation. The subject device applies rule-based decision logic to these segmentation results to generate binary outputs indicating the presence or absence of synovial hypertrophy, Doppler activity, and osteophytes. In contrast, the predicate device derives measurements of anatomical structure thickness from the generated segmentations and does not apply classification or decision logic.

Although the subject device applies rule-based decision logic to generate binary clinical decision support outputs, whereas the predicate device provides anatomical measurements without classification or decision logic, these technological differences do not raise different questions of safety or effectiveness. Based on the similarities in intended use, underlying segmentation technology, performance validation, and overall technological characteristics, the subject device is substantially equivalent to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device applies a predefined and standardized methodology for the evaluation of ultrasound images to support the assessment of possible musculoskeletal disease activity. Binary disease activity classification is performed for synovial hypertrophy, Doppler activity, and osteophytes based on the EULAR OMERACT scoring system with the cut-off values:
- Synovial hypertrophy: grade 0 and 1 would classify as absence of disease. Grade 2 and 3 is classified as presence of disease
- Synovial Doppler activity: grade 0 would classify as absence of disease. Grade 1, 2 and 3 is classified as presence of disease
- Osteophytes: grade 0 and 1 would classify as absence of disease. Grade 2 and 3 is classified as clinical presence of the disease.

The presence or absence of disease parameters is provided to the clinician as structured textual information along with corresponding visual output. In addition, the subject device provides a historical view of disease presence to support longitudinal clinical assessment. These outputs are intended to support clinical review and decision-making by qualified healthcare professionals and do not replace clinical judgment. The subject device further provide the healthcare professional with presents the underlying ultrasound images, so that the clinician can independently verify each analysis against the ultrasound image. The clinician is advised to access the ultrasound images within the report and include other diagnostic parameters.

The technological characteristics, mode of operation, and output of the subject device are comparable to those of the predicate device and do not raise any new or different questions of safety or effectiveness.

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

Performance testing was conducted to demonstrate that DIANA performs as specified in the intended use.
Usability testing was performed to evaluate user comprehension and interpretation of the device outputs. The results demonstrated that intended users were able to understand and interpret the clinical decision support results, including the anatomical segmentations displayed as overlays on the original ultrasound images. The usability evaluation demonstrated that the presentation of the results supports transparent interpretation and clinical review by healthcare professionals trained and qualified in musculoskeletal (MSK) ultrasound.

Validation testing was performed using independent datasets collected from multiple clinical sites, representative patient populations, and different ultrasound systems to evaluate the generalizability of the algorithms across representative clinical settings.
The performance validation dataset consisted of more than 6,000 ultrasound data points (B-mode images and Doppler videos) obtained from more than 1,800 patient examinations (72.4% female and 27.6% male). The dataset included examinations acquired at hospitals in Denmark (46%), Germany (39%), and the United States (15%) using GE LOGIQ E10, GE LOGIQ Totus, and Canon Aplio A ultrasound systems. The validation dataset included metacarpophalangeal (MCP), proximal interphalangeal (PIP), distal interphalangeal (DIP), and radiocarpal/intercarpal (RCIC) joints.

Device performance was evaluated by comparison with a reference standard established by up to five musculoskeletal ultrasound experts, each with more than 10 years of clinical experience. The reference standard was established using the EULAR-OMERACT ultrasound scoring system. For performance evaluation, the expert OMERACT scores were converted to binary classifications (presence or absence) for synovial hypertrophy, Doppler activity, and osteophytes. DIANA provides binary clinical decision support indicating the presence or absence of these findings.

The clinical performance of the device is defined by the mean sensitivity and specificity for the detection of synovial hypertrophy, osteophytes, and Doppler activity. DIANA demonstrated a sensitivity of 0.70 (95% CI: 0.64–0.77) and a specificity of 0.91 (95% CI: 0.88–

0.93) for synovial hypertrophy. For osteophyte detection, the sensitivity was 0.78 (95% CI: 0.73–0.83) and the specificity was 0.84 (95% CI: 0.79–0.91). For Doppler activity, DIANA achieved a sensitivity of 0.82 (95% CI: 0.62–0.94) and a specificity of 0.97 (95% CI: 0.94–1.00).

Performance testing demonstrated that DIANA performs as intended by providing binary clinical decision support for the assessment of synovial hypertrophy, Doppler activity, and osteophytes from pre-captured ultrasound images of the hand and wrist. The device achieved high specificity across all three assessment categories 0.84–0.97, while maintaining sensitivities between 0.70 and 0.82.

The subject device and the predicate device are software-based medical devices intended to provide analysis of pre-captured musculoskeletal ultrasound images using non-adaptive (locked) artificial intelligence algorithms. Both devices employ image segmentation to identify musculoskeletal anatomical structures. The resulting segmentations are used to generate device-specific outputs that support interpretation by healthcare professionals trained in musculoskeletal (MSK) ultrasound.

The subject device is intended for use with ultrasound images of the hand and wrist, whereas the predicate device is intended for a different musculoskeletal anatomical region. This difference in anatomical site does not raise different questions of safety or effectiveness because both devices analyze musculoskeletal ultrasound images with comparable imaging characteristics using the same technological approach. Both devices utilize locked AI algorithms and provide anatomical segmentations for user review. The predicate device derives anatomical measurements from the segmentations, whereas the subject device applies rule-based decision logic to generate binary clinical decision support outputs.

Performance validation of the subject device was conducted using independent multicenter datasets representative of the intended patient population. The validation results demonstrated that the subject device performs as intended for its intended use and support that the differences in anatomical site do not adversely affect the safety or effectiveness of the device.

Although the subject device differs from the predicate by applying rule-based decision logic to segmentation results to generate binary clinical decision support outputs, whereas the predicate provides anatomical measurements derived from segmentation, these technological differences do not raise new questions of safety or effectiveness.
Based on the similarities in intended use, underlying segmentation technology, mode of operation, and performance testing, the subject device is considered substantially equivalent to the predicate device.