September 20, 2021

Radiobotics ApS
% John Smith
Partner
Hogan Lovells US LLP
555 13th Street, NW
Washington, District of Columbia 20004

Re: K203696
Trade/Device Name: RBknee
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ, JAK

Dear John Smith:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 27th, 2021. Specifically, FDA is updating this SE Letter due to the SE package containing the wrong version of the 510(k) Summary and Indications for Use statement.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Thalia Mills, OHT7: Office of In Vitro Diagnostics and Radiological Health by email (Thalia.Mills@fda.hhs.gov) or phone (301-796-6641).

Sincerely,

Laurel M. Burk -S

Digitally signed by Laurel M. Burk -S
Date: 2021.09.20 09:15:35 -04'00'

Laurel Burk
Chief
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Radiobotics ApS
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 13th Street, NW
WASHINGTON DC 20004

August 27, 2021

Re: K203696
Trade/Device Name: RBknee
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ, JAK
Dated: June 1, 2021
Received: June 1, 2021

Dear Dr. Smith:

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,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*
K203696

Device Name
RBknee

Indications for Use *(Describe)*

RBknee is a radiological fully automated image processing software device of either computed (CR) or directly digital (DX) images intended to aid medical professionals in the measurement of minimum joint space width; the assessment of the presence or absence of sclerosis, joint space narrowing, and osteophytes based on OARSI criteria for these parameters; and, the presence or absence of radiographic knee OA based on Kellgren-Lawrence grading of standing, fixed-flexion radiographs of the knee.

It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis.

The system is to be used by trained professionals including, but not limited to, radiologists, orthopedics, physicians and medical technicians.

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.

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Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

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510(k) SUMMARY
Radiobotics Aps's RBknee

Submitter

Radiobotics ApS

Esplanaden 8C, 1-tv,
1263 Copenhagen,
Denmark

Phone: +45 26 14 61 84

Contact Person: Martin Christian Axelsen, PhD; Co-founder & CSO

Date Prepared: June 1, 2021

Name of Device: RBknee

Trade/proprietary name of device: RBknee

Common or Usual Name: System, Image Processing, Radiological

Classification Name: Medical Image Management and Processing System (892.2050)

Regulatory Class: Class II

Product Codes: LLZ, JAK

Classification Advisory Committee: Radiology

Predicate Device: IB Lab GmbH, KOALA (K192109)

Intended Use / Indications for Use

RBknee is a radiological fully automated image processing software device of either computed (CR) or directly digital (DX) images intended to aid medical professionals in the measurement of minimum joint space width; the assessment of the presence or absence of sclerosis, joint space narrowing, and osteophytes based on OARSI criteria for these parameters; and, the presence or absence of radiographic knee OA based on Kellgren-Lawrence grading of standing, fixed-flexion radiographs of the knee.

It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis.

The system is to be used by trained professionals including, but not limited to, radiologists, orthopedics, physicians and medical technicians.

Technological Characteristics

In general, the technological characteristics of the RBknee is directly comparable to the predicate device, KOALA.

Similar to KOALA, RBknee as a fully-automated image processing stand-alone software is a software device designed to assist clinicians in analyzing and measuring radiographic abnormalities during review of posterior-anterior (PA) and anterior-posterior (AP) radiographs.

The predicate and subject software utilize computer vision and machine learning algorithms trained on medical images. The machine-learning algorithms allow for high accuracy in the detection and measurement of OA related symptoms visible on knee radiographs.

In brief, RBknee takes digital radiographs (AP/PA) as input and as output provides:

1. A visual report with
    a. A copy of regions of interest from the original radiographs with overlays that mark the minimum Joint Space Width (JSW)
    b. A table with the measurement of the minimum JSW in millimeters (mm), information on the presence or absence of joint space narrowing, osteophytes, and sclerosis based on OARSI gradings, and information on the presence or absence of radiographic knee osteoarthritis (OA) based on the Kellgren-Lawrence (KL) score.

2. A text report with
    a. A textual summary of the presence or absence of joint space narrowing, osteophytes, and sclerosis based on OARSI gradings (called findings), and a textual summary of the presence or absence of radiographic knee osteoarthritis (OA) based on the Kellgren-Lawrence score (called impression).

RBknee is not interpreting any results but makes an objective measurement and providing an output based on a well established scale (OARSI/KL).

RBknee can be integrated to a PACS and the outputs of RBknee can be reviewed in a DICOM viewer.

RBknee operates in a Linux environment and can be deployed to be compatible with any operating system supporting the third-party software Docker. The integration environment has to support RBknee data input and output requirements. The device does not interact with the patient directly, nor does it control any life-sustaining devices.

Performance Data

Software verification and validation testing was completed for the subject device. The software functioned as intended and all results observed were as expected.

A standalone clinical performance validation of RBknee was performed using the open-access database from the Osteoarthritis Initiative (OAI), a large U.S. prospective multicenter observational study conducted over a period of 12 years. Ground truth grading for Kellgren Lawrence grades, as well as osteophyte, sclerosis and joint space narrowing grades according to the OARSI (Osteoarthritis Research Society International) guidelines, and measurements of the minimum joint space width was established by two physicians following adjudication procedures with a third reviewer for discrepancies.

The performance of RBknee for the status indicators of the radiographic findings are listed in the table below.

	RBknee				
	Data Support (images/ unique subjects)	Sensitivity		Specificity	
Kellgren-Lawrence status*	4279/421	0.88		0.87	
95% CI		0.85	0.91	0.84	0.89
Joint Space Narrowing Status#	4279 / 421	0.82		0.87	
95% CI		0.79	0.86	0.84	0.90
Osteophytosis status#	2427/289	0.89		0.78	
95% CI		0.87	0.91	0.72	0.84
Subchondral Sclerosis status#	2329/272	0.84		0.87	
95% CI		0.80	0.87	0.84	0.90
*** KL-grade ≥ 2** **# OARSI-grade > 0**					

The accuracy of the measurements of the minimum Joint Space Width by RBknee was quantified using orthogonal linear regression by comparing the measurements by RBknee with equivalent measurements from the OAI. The slope and intercept can be seen in the table below.

	RBknee			
	Slope		Intercept	
Medial	1.00		-0.07	
Medial, 95%CI	0.98	1.02	-0.17	0.03
Lateral	1.00		-0.10	
Lateral, 95%CI	0.97	1.03	-0.27	0.06

Summary

- Software verification and validation testing was completed for the subject device. The RBknee functioned in all instances as intended and all results observed were as expected.
- RBknee is an effective image processing device that provides reliable measurements and accurate indicators for presence/absence of radiographic features relevant for the analysis of radiographic knee osteoarthritis. Thus, the device performs as intended and is substantially equivalent to the predicate device.

Substantial Equivalence

The RBknee is as safe and effective as the KOALA. The RBknee has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Performance data demonstrates that the RBknee is as safe and effective as KOALA. Thus, the RBknee is substantially equivalent.

Conclusions

In conclusion, RBknee is as safe, as effective, and performs as well as the predicate device, KOALA. The RBknee has a similar intended use, indication, technological characteristics, and principles of operation as KOALA. The differences between RBknee and KOALA do not alter the intended use of the device and do not raise new or different questions regarding its safety and effectiveness when used as labelled. Performance data demonstrates that the device performs as intended. Thus, RBknee is substantially equivalent.