IB Lab GmbH
℅ Richard Ljuhar
Official Correspondent
Zehetnergasse 6/2/2
Vienna, 1140
AUSTRIA

June 16, 2023

Re: K223646
Trade/Device Name: IB Lab LAMA
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: May 17, 2023
Received: May 17, 2023

Dear Richard Ljuhar:

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 and Part 809); 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,

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

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)*
K223646

Device Name
IB Lab LAMA

Indications for Use *(Describe)*
IB Lab LAMA is a fully-automated radiological image processing software device intended to aid users in the measurement of limb-length discrepancy and quantitative knee alignment parameters on uni- and bilateral AP full leg radiographs of individuals at least 22 years of age. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The software device is intended to be used by healthcare professionals trained in radiology.
IB Lab LAMA is not indicated for use on radiographs on which Ankle Arthroplasties and/or Unicompartmental Knee Arthroplasties are present.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."*

# 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

**Submitter Information** 807.92(a)(1)

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Contact Person: Dr. Richard Ljuhar
Date: 02. December 2022

807.92(a)(2)

Trade Name: IB Lab LAMA
Common Name: AI supported Leg Geometry Measurement Assistant
Classification Name(s): Medical image management and processing system (per 21 CFR section 21 CFR 892.2050)
Product Code: QIH

**Predicate Devices/ Reference Devices** 807.92(a)(3)

| | **predicate device** |
|---|---|
| **Manufacturer:** | IB Lab GmbH<br>Zehetnergasse 6/2/2<br>1140 Wien<br>Austria |
| **Trade Name** | KOALA |
| **510(k) document control number** | K192109 |
| **Device Class** | Class II |
| **Granted marketing clearance by FDA** | Yes |
| **Product code** | LLZ/892.2050,<br>JAK/892.1750 |
| **Clearance Date** | November 6, 2019 |

**Device Description** 807.92(a)(4)

IB Lab LAMA uses deep learning technology to provide precise fully-automated geometric length and angle measurements of the lower limb on full leg X-ray images. The outputs aid healthcare professionals who are interested in the analysis of leg-length discrepancy and knee alignment in adult patients with suspected or present deformities of the lower extremities. IB Lab LAMA provides the following measurements:

- mechanical axis deviation
- full leg length
- femur length
- tibia length
- leg length discrepancy
- hip knee ankle angle
- anatomical tibiofemoral angle
- anatomical mechanical angle
- joint-line convergence angle
- mechanical lateral proximal femoral angle
- mechanical lateral distal femoral angle
- mechanical medial proximal tibia angle
- mechanical lateral distal tibia angle

The user does not interact directly with IB Lab LAMA except to accept or reject the generated report findings via cleared third party medical viewers. The measurements are compared to fixed predetermined norm-ranges, based on standard state of the art clinical practices hard-coded into the software. Outputs are summarized in reports that can be viewed on any cleared medical DICOM viewer. IB Lab LAMA operates in a Linux environment and can be deployed on any operating system that supports the third-party software Docker. The integration environment has to support IB Lab LAMA data input and output requirements. The device does not interact with the patient directly, nor does it control any life-sustaining devices.

**Intended Use / Indications for Use** 807.92(a)(5)

> *IB Lab LAMA is a fully-automated radiological image processing software device intended to aid users in the measurement of limb-length discrepancy and quantitative knee alignment parameters on uni- and bilateral AP full leg radiographs of individuals at least 22 years of age. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The software device is intended to be used by healthcare professionals trained in radiology.*

*IB Lab LAMA is not indicated for use on radiographs on which Ankle Arthroplasties and/or Unicompartmental Knee Arthroplasties are present.*

## Comparison of the Technological Characteristics with the Predicate Devices 807.92(a)(6)

| Characteristic | KOALA<br>IB Lab GmbH<br>Predicate Device (K192109) | IB Lab LAMA<br>IB Lab GmbH<br>Subject Device | Discussion of Differences |
|---|---|---|---|
| *Indications for use* | IB Lab KOALA 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 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. | IB Lab LAMA is a fully-automated radiological image processing software device intended to aid users in the measurement of limb-length discrepancy and quantitative knee alignment parameters on uni- and bilateral AP full leg radiographs of individuals at least 22 years of age. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The software device is intended to be used by healthcare professionals trained in radiology.<br>IB Lab LAMA is not indicated for use on radiographs on which Ankle Arthroplasties and/or Unicompartmental Knee Arthroplasties are present. | The subject device performs measurements of lengths and angles on full leg images. The predicate device performs length and grade measurements on knee images. This difference in specific anatomic locations does not raise new types of questions for safety or effectiveness and therefore does not induce changes in the intended use. For both devices, the key question is whether the software is able to generate accurate and reproducible anatomical measurements within the target population. |

| Characteristic | KOALA<br>IB Lab GmbH<br>Predicate Device (K192109) | IB Lab LAMA<br>IB Lab GmbH<br>Subject Device | Discussion of Differences |
|---|---|---|---|
| *Product code* | LLZ/892.2050, JAK/892.1750 | QIH/892.2050 | Similar. The product code QIH was not yet available when the predicate was cleared. |
| *Human Intervention for interpretation* | Required | Required | Same. |
| *Image Requirements* | DICOM compliant images collected in other devices in either digitally computed (CR) or directly digital (DX) formats | DICOM compliant plain radiographs collected in other devices in the CR, DX, SC formats. | Similar. This difference does not raise new questions about safety since the additional format SC is standardly used for processed DICOM images. For long-leg radiographs post-processing is the standard since the images are generally assembled by cleared medical software. |
| *Anatomical area* | knee | full leg | Similar. The anatomical region does not raise new questions regarding safety or effectiveness with respect to the technological characteristics. The techniques used for capturing full leg images and knee images are both standard procedures. |
| *Workflow / Principles of Operation* | 1. User or PACS sends image to device<br>2. Device performs analysis<br>3. Image is sent back to PACS<br>4. User reviews and accepts/rejects report | 1. User or PACS sends image to device<br>2. Device performs analysis<br>3. Image is sent back to PACS<br>4. User reviews and accepts/rejects report | Same. |

| Characteristic | KOALA<br>IB Lab GmbH<br>Predicate Device (K192109) | IB Lab LAMA<br>IB Lab GmbH<br>Subject Device | Discussion of Differences |
|---|---|---|---|
| *Processing Architecture* | 1. Pre-process the input image<br>2. Classify uni or bilateral image<br>3. Compute regions of interest for each side.<br>4. Detect landmarks and segmentations<br>5. Compute distances<br>6. Compute OA parameters<br>7. Generate reports | 1. Pre-process the input image<br>2. Classify uni or bilateral image<br>3. Compute regions of interest for each side.<br>4. Detect landmarks and segmentations<br>5. Compute lines and distances<br>6. Compute angles<br>7. Generate reports | 1. Same.<br>2. Same.<br>3. Same.<br>4. Same.<br>5. Similar. The subject also visualizes lines of which distances are measured and thus raises no new questions regarding safety and effectiveness. Standalone performance testing is performed to show that the subject device performs as intended. See **Section 20: Performance Testing - Clinical**.<br>6. The predicate measures OA parameters (grades), while the subject computes angles. Standalone performance testing is performed to show that the subject device performs as intended. See **Section 20: Performance Testing - Clinical**.<br>7. Same |
| *Technology* | ● Convolutional neural networks for<br>○ classification<br>○ landmarking<br>○ segmentation<br>○ grading | ● Convolutional neural networks for<br>○ classification<br>○ landmarking<br>○ segmentation<br>● Classical methods for computing:<br>○ auxiliary points<br>○ lengths | ● Similar. The technology of the subject device is contained in the predicate and thus raises no new questions regarding safety and effectiveness. Standalone performance testing is performed to show that the subject device performs as intended. See **Section 20: Performance Testing - Clinical** |

| Characteristic | KOALA<br>IB Lab GmbH<br>Predicate Device (K192109) | IB Lab LAMA<br>IB Lab GmbH<br>Subject Device | Discussion of Differences |
|---|---|---|---|
| | ● Classical methods for computing:<br>○ auxiliary points<br>○ lengths | ○ angles | ● Similar. Angles are computed using standard classical methods from lines and thus raises no new questions regarding safety and effectiveness. Standalone performance testing is performed to show that the subject device performs as intended. See **Section 20: Performance Testing - Clinical**. |
| *Output* | Human and machine readable reports in the DICOM format | Human and machine readable reports in the DICOM format | Same. |
| *Physical Characteristics* | Software application operated on OTS hardware. | Software application operated on OTS hardware. | Same. |
| *Safety* | displayed warnings | displayed warnings | Same. |
| | intended user: qualified and trained healthcare professionals | intended user: qualified and trained healthcare professionals | Same. |
| | Automated input checks: Dicom tags check | Automated input checks: Dicom tags check | Same. |

807.92(b)(1)
Product verification and validation testing was completed for the subject device.
The non-clinical tests included unit, integration testing as well as system level tests. The performance of the individual deep-neural networks was tested on hold-out sets. The performance of the software outputs was not tested in this non-clinical setting. Product validation was performed via questionnaires.
The software functioned as intended and all results observed were as expected. The device documentation was created in accordance with the *FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005)* for a Moderate Level of Concern software. All software requirements and risk analysis have been successfully verified and traced.

807.92(b)(2)
To validate the outputs of IB Lab LAMA, a clinical data-based standalone performance study was conducted in the U.S. The Standalone performance testing (SPT) was performed on an image dataset composed of 189 radiographs of bilateral AP lower extremity radiographs of adults, with and without hip or knee implants, obtained from US clinical sites affiliated with the University of Texas Southwestern Medical Center (UTSW) resulting in 325 legs.
The ground truths for the measurements were independently established by two US Board certified musculoskeletal radiologists with at least 5 years post-fellowship expertise in the assessment of lower limb length and alignment on AP lower extremity radiographs, without using IB Lab LAMA outputs. The truthers were further blinded to the assessments from the clinical report as well as the readings from the other truthers. The truther measurements were averaged to form the ground truth. If any pair of assessments differs by more than the threshold defined in the Test-Plan, the respective leg was consensus read by the two truthers in order to establish a reliable ground truth.

The SPT compares IB Lab LAMA's angle and length measurements to the ground truth using Bland-Altman plots, and by computing the interchangeability and intra-class correlation coefficient (ICC) for each measurement.

| **IB Lab LAMA vs. GT - Primary Objective: Agreement** | | | | | | |
|---|---|---|---|---|---|---|
| **Variable** | **Unit** | **No.[1]** | **Mean Diff.** | **Std. Dev.** | **Lower LOA** | **Upper LOA** |

[1] For the LLD measurement the No. column corresponds to the number of images. For all other measurements it corresponds to the number of legs.

| | | | | | (lower CI) | (upper CI) |
|---|---|---|---|---|---|---|
| **MAD** | **[mm]** | 244 | -1.37 | 2.54 | -6.89 | 4.15 |
| **Femur Length** | **[cm]** | 208 | 0.09 | 0.16 | -0.26 | 0.45 |
| **Tibia Length** | **[cm]** | 244 | 0.01 | 0.13 | -0.27 | 0.28 |
| **Leg Length** | **[cm]** | 208 | 0.05 | 0.12 | -0.23 | 0.32 |
| **LLD** | **[mm]** | 77 | 0.13 | 1.4 | -3.16 | 3.43 |
| **HKA** | **[°]** | 244 | -0.19 | 0.73 | -1.79 | 1.4 |
| **aTFA** | **[°]** | 244 | -0.51 | 1.18 | -3.08 | 2.05 |
| **AMA** | **[°]** | 244 | 0.06 | 0.89 | -1.88 | 1.99 |
| **JLCA** | **[°]** | 244 | 0.22 | 1.35 | -2.72 | 3.15 |
| **mLPFA** | **[°]** | 208 | 2.48 | 2.45 | -2.89 | 7.85 |
| **mLDFA** | **[°]** | 244 | -0.37 | 0.96 | -2.46 | 1.72 |
| **mMPTA** | **[°]** | 244 | -0.01 | 1.28 | -2.79 | 2.77 |
| **mLDTA** | **[°]** | 244 | -0.62 | 2.05 | -5.08 | 3.85 |

| **IB Lab LAMA - Secondary Objective** | |
|---|---|
| **Arthroplasty Detection (TKA and THA)** | |
| **Sensitivity** | **Specificity** |
| 95.05%<br>(90.29%, 98.96%) | 99.80%<br>(99.39%, 100.00%) |
| **Failure Rate** | |

| |
|---|
| n = 9 of 324 legs failed; failure rate ~ 2.8 % (5%) |
| **Repeatability Testing** |
| No differences between repeated runs. |

In summary, the standalone performance testing results demonstrate that IB Lab LAMA provides clinically relevant measurements of angles and lengths on long leg radiographs. The standalone performance testing results establish that IB Lab LAMA is an effective image processing device that provides reliable measurements of angles and lengths. Thus, the device performs as intended and is substantially equivalent to the predicate device.

**Conclusion** 807.92(b)(3)
IB Lab LAMA is as safe and effective as the predicate device. The subject device has the same intended use and principles of operation; furthermore, it has similar indications and technological characteristics as its predicate device. The minor differences between subject and predicate device in indications do not alter the intended use of the subject device and do not raise new or different questions regarding its safety and effectiveness when used as labeled. Performance data demonstrate that the device performs as intended.
Verification and validation testing, including the standalone software performance test, supports the safety of the device and demonstrates that IB Lab LAMA performs as intended. Therefore, IB Lab LAMA is substantially equivalent.