August 17, 2026

S.M.A.I.O
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-De-L'Ile-Perrot, QC J7W3J6
Canada

Re: K261500
Trade/Device Name: KBA3D (v2.4.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 15, 2026
Received: July 15, 2026

Dear Robert Poggie:

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. | K261500 |

Please provide the device trade name(s).

KBA3D (v2.4.0)

Please provide your Indications for Use below.

The KBA3D v2.4.0 is intended for assisting healthcare professionals in viewing X-ray images, identifying spinal anatomical structures, simulating surgical correction strategies, and defining the geometry of patient-specific implants (such as rods) based on the surgeon's validated surgical plan.
The device allows users to:
• Manually identify anatomical structure on X-ray images
• Perform spine-related measurements
• Manually simulate surgical correction procedures
• Design customized implant geometry
Clinical judgment and experience are required to properly use the software.

| | |
|---|---|
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |
| Please select the age group(s) for which the device(s) is to be used. | ☐ Neonates/Newborns (Birth to < 29 days old)<br>☐ Infants (29 days old to < 2 years old)<br>☐ Children (2 years old to < 12 years old)<br>☒ Adolescents (12 years old to < 22 years old)<br>☒ Adults (22 years old and greater) |

K261500

# 510(k) Summary

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following is a summary of safety and effectiveness of S.M.A.I.O's KEOPS Balance Analyzer 3 (KBA3D v2.4.0).

## A. SUBMITTERS INFORMATION

| | |
|---|---|
| **Submitter Name:** | BioVera, Inc. |
| **Submitter Address:** | 65 Promenade Saint-Louis, NDIP, Québec, J7W 3J6, CANADA |
| **Contact Person:** | Robert A. Poggie, PhD |
| **Phone Number:** | 514-349-7226 |
| **Date of Submission:** | July 13, 2026 |

## B. DEVICE IDENTIFICATION & MANUFACTURER

| | |
|---|---|
| **Manufacturer Name:** | S.M.A.I.O |
| **Manufacturer Address:** | 2 place Berthe Morisot - Parc Technologique<br>69800 Saint Priest - FRANCE |
| **Registration Number:** | 3015383864 |
| **Contact Name:** | Jean-Charles ROUSSOULY |
| **Title:** | Deputy CEO |
| **Device Trade Name:** | KEOPS Balance Analyzer 3D (KBA3D v2.4.0) |
| **Regulation Name:** | Picture archiving and communications system 21 |
| **Regulation Numbers:** | CFR 892.2050 |
| **Classification Codes:** | LLZ |
| **Classification Panel:** | Radiology Devices |

## C1. PRIMARY PREDICATE DEVICE

| | |
|---|---|
| **K223841** | KEOPS Balance Analyzer 3D (KBA3D v2.0.0) |

## C2. ADDITIONAL PREDICATE DEVICE

| | |
|---|---|
| **K213975** | KEOPS Balance Analyzer 3D (KBA3D) |

## D. DEVICE DESCRIPTION

The subject device KEOPS Balance Analyzer 3D (KBA3D v2.4.0) is a SaaS software solution developed by SMAIO for the medical community; it is a second, independent version of the original KBA3D v2.0.0 cleared by FDA in K223841. The software supports the design of the patient-specific K-ROD rods, which was previously cleared by FDA in K211981.

## E. INDICATIONS FOR USE

The KBA3D v2.4.0 is intended for assisting healthcare professionals in viewing X-ray images, identifying spinal anatomical structures, simulating surgical correction strategies, and defining the geometry of patient-specific implants (such as rods) based on the surgeon's validated surgical plan.

The device allows users to:

- Manually identify anatomical structure on X-ray images
- Perform spine-related measurements
- Manually simulate surgical correction procedures
- Design customized implant geometry

Clinical judgment and experience are required to properly use the software.

KBA3D v2.4.0 software is indicated for assisting spine pathologies diagnostic and spinal surgeries planification.

KBA3D v2.4.0 aims to achieve three objectives:

1. From an upright coronal and sagittal 2D X-ray that contains the patient's vertebral anatomy from femoral heads to the cervical levels (included), KBA3D creates a calibrated 3D rendering of the spine. The software provides related shape and positioning parameter measurements which include disc and vertebral height and angulation, main curvatures and global balance assessment.
2. Simulate potential effects of a spine surgery on spinopelvic alignment and provide related shape and positioning parameters calculation.
3. Visualize implant positioning relative to spinopelvic representation (pre-op versus realigned) to establish possible implant selection scenarios.

## F. TECHNOLOGICAL CHARACTERISTICS, COMPARISON TO PREDICATE DEVICE

The subject device has similar fundamental scientific technology, overall design, features, computer configuration characteristics, intended use, and indications as the primary predicate device. The main software modifications incorporated into KBA3D v2.4.0, as compared with the primary predicate device, are summarized below:

- Addition of Quick Measurements module for user to perform measurements (distance, diameter, angle, plumbline) on X-rays.
- Addition of automatic generation of a surgical plan report in pdf.
- Addition of representation of the cervical vertebrae in the 3D viewport.
- Addition of C2PA line on the 3D viewport.
- Addition of automatic generation of a printable rod template.
- Removal of communication between KBA3D and BENDINI API and all the representation of the BENDINI rod (in the sagittal, coronal and 3D viewports).
- Removal of screws and cages modules.
- Removal of patient's initials from the top-of-page header band.
- Update of KBA3D theme with SMAIO colors.
- Adaptation of the viewer module to mobile devices (smartphones and tablets).

The subject device and the primary predicate and the additional predicate devices are compared in the table below:

| Characteristic | Additional Predicate Device (KBA3D v1.1.3) | Primary Predicate (KBA3D v2.0.0) | Subject Device (KBA3D v2.4.0) | Substantially Equivalent? |
|---|---|---|---|---|
| Intended Use | The KEOPS Balance Analyzer 3D is intended for assisting healthcare professionals in viewing and measuring images as well as planning spine surgeries. The device allows surgeons and service providers to perform spine related measurements on images and to plan surgical procedures. The device also includes tools for measuring anatomical components for design and placement of surgical implants. Clinical judgment and experience are required to properly use the software. | KBA3D V2.0.0 software can be used by health professionals (orthopedic surgeons, radiologists, neurosurgeons) and service providers (imaging technicians, clinical study technicians) who are trained in spine imaging and pathologies. The KBA3D V2.0.0 software is intended for patients requiring imaging measurements and planning of surgical procedures. KBA3D v2.0.0 aims to achieve three objectives:<br>1. From two perpendicular patient's standing x-rays including patient's spine and pelvis from the femoral heads to the cervical levels, provide | The KBA3D v2.4.0 is intended for assisting healthcare professionals in viewing X-ray images, identifying spinal anatomical structures, simulating surgical correction strategies, and defining the geometry of patient-specific implants (such as rods) based on the surgeon's validated surgical plan.<br>The device allows users to:<br>• Manually identify anatomical structure on X-ray images<br>• Perform spine-related measurements<br>• Manually simulate surgical | YES – The subject and predicate devices have the same intended use and equivalent core functionalities (spine measurements, surgical simulation and design and placement of surgical implants).<br>Differences in wording do not impact functionality. |

| Characteristic | Additional Predicate Device (KBA3D v1.1.3) | Primary Predicate (KBA3D v2.0.0) | Subject Device (KBA3D v2.4.0) | Substantially Equivalent? |
|---|---|---|---|---|
| | | 3D scaled representation of the femoral heads, sacral plate, and vertebral bodies. Provide related shape and positioning parameters measurements (disc/vertebra/height/angulation), main curvatures description and global balance assessment.<br>2. Simulate potential effects of a spine surgery on spinopelvic alignment and provide related shape and positioning parameters calculation.<br>3. Visualize scaled representation of implant range (pedicle screws, interbody cages, union rods) relative to spinopelvic representation (pre-op versus realigned) to establish possible implant selection scenarios. | correction procedures<br>• Design customized implant geometry<br>Clinical judgment and experience are required to properly use the software.<br>KBA3D v2.4.0 software is for assisting spine pathologies diagnostic and spinal surgeries planning. KBA3D v2.4.0 aims to achieve three objectives:<br>1. From an upright coronal and sagittal 2D X-ray that contains the patient's vertebral anatomy from femoral heads to the cervical levels (included), KBA3D creates a calibrated 3D rendering of the spine. The software provides related shape and positioning parameter measurements which include disc and vertebral height and angulation, main curvatures and global balance assessment.<br>2. Simulate potential effects of a spine surgery on spinopelvic alignment and provide related shape and positioning parameters calculation.<br>3. Visualize implant positioning relative to spinopelvic representation (pre-op versus realigned) to establish possible implant selection scenarios. | |
| Indications for use | The KEOPS Balance Analyzer 3D is intended for assisting healthcare professionals in viewing and measuring images as well as planning spine surgeries. The device allows surgeons and service providers to perform spine related measurements on images and to | The KBA3D v2.0.0 is intended for assisting healthcare professionals in viewing and measuring images as well as planning spine surgeries. The device allows surgeons and service providers to perform spine related measurements on images, and to plan surgical procedures. The | The KBA3D v2.4.0 is intended for assisting healthcare professionals in viewing X-ray images, identifying spinal anatomical structures, simulating surgical correction strategies, and defining the geometry of patient-specific implants (such as rods) based on | YES – The subject and predicate devices have the same indications for use and equivalent core functionalities (spine measurements, surgical simulation and |

| Characteristic | Additional Predicate Device (KBA3D v1.1.3) | Primary Predicate (KBA3D v2.0.0) | Subject Device (KBA3D v2.4.0) | Substantially Equivalent? |
|---|---|---|---|---|
| | plan surgical procedures. The device also includes tools for measuring anatomical components for design and placement of surgical implants. Clinical judgment and experience are required to properly use the software. | device also includes tools for measuring anatomical components for design and placement of surgical implants. Clinical judgment and experience are required to properly use the software.<br>The patient population targeted with the use of the KBA3D v2.0.0 software includes patients with mature skeletons requiring imaging measurements and planning of surgical procedures. The Bendini Rod Bending algorithm is intended for patients older than 22 years old. | the surgeon's validated surgical plan.<br>The device allows users to:<br>• Manually identify anatomical structure on X-ray images<br>• Perform spine-related measurements<br>• Manually simulate surgical correction procedures<br>• Design customized implant geometry<br>Clinical judgment and experience are required to properly use the software. | design/definition and placement of surgical implants).<br>Differences in wording do not impact the indications for use. |
| Regulatory Class/Code | Class II<br>LLZ /21 CFR 892.2050 | Class II<br>LLZ /21 CFR 892.2050 | Class II<br>LLZ /21 CFR 892.2050 | YES |
| Fundamental scientific technology | Standalone software | Standalone software | Standalone software | YES |
| Health Data Host | AWS | AWS | AWS | YES |
| Frontend code | HTML CSS JQuery | VueJS | VueJS | YES, KBA3D v2.4.0 uses the same frontend framework as the predicate device (v2.0.0). Compared to the additional predicate device (v1.1.3), migration represents a technology modernization only. |
| Backend code | PHP | PHP | PHP | YES |
| Databases server | AWS RDS for MySQL | AWS RDS for MySQL | AWS RDS for MySQL | YES |
| Device Classification | Medical image management and processing system | Medical image management and processing system | Medical image management and processing system | YES |

| Characteristic | Additional Predicate Device (KBA3D v1.1.3) | Primary Predicate (KBA3D v2.0.0) | Subject Device (KBA3D v2.4.0) | Substantially Equivalent? |
|---|---|---|---|---|
| Name | | | | |
| Operating System | Windows + MAC | Windows + MAC | Windows + MAC | YES |
| Software Environment | Cloud-based software | Cloud-based software | Cloud-based software | YES |
| Image Input | Local | Local | Local | YES |
| Input Data | Patient information<br>X-ray | Patient information<br>X-ray | Patient information<br>X-ray | YES |
| Runs on server | Yes | Yes | Yes | YES |
| User Population | KEOPS Balance Analyzer 3D software can be used by health professionals (orthopaedic surgeons, neurosurgeons). | KBA3D v2.0.0 software can be used by health professionals (orthopedic surgeons, neurosurgeons, radiologists), trained for the spine imaging and pathologies and by service providers (imaging technician, clinical study technician) also trained for spine imaging and pathologies. | KBA3D v2.4.0 software can be used by healthcare professionals (orthopaedic surgeons, neurosurgeons, radiologists), trained on spine imaging and pathologies and by service providers (imaging technician, clinical study technician) also trained on spine imaging and pathologies. | YES – Same user population, wording differences only |
| Target Population | KEOPS Balance Analyzer 3D software is suitable for patients suffering from back pain requiring surgical treatment or conservative orthopaedic treatment. | The patient population targeted with the use of the KBA3D v2.0.0 software includes patients with mature skeletons requiring imaging measurements and planning of surgical procedures.<br>The Bendini Rod Bending algorithm is intended for patients older than 22 years old. | The patient population targeted with the use of the KBA3D v2.4.0 software includes patients requiring imaging measurements and planning of surgical procedures. | YES – The subject device and the primary predicate target patients requiring imaging measurements and planning of surgical procedures.<br>The additional predicate device (K213975) supports use in patients requiring orthopaedic treatment without restriction to mature skeletons.<br>The removal of the “mature skeletons” limitation in the subject device is consistent with the patient population of |

| Characteristic | Additional Predicate Device (KBA3D v1.1.3) | Primary Predicate (KBA3D v2.0.0) | Subject Device (KBA3D v2.4.0) | Substantially Equivalent? |
|---|---|---|---|---|
| | | | | the additional predicate device.<br>The predicate device also included a module (Bendini) restricted to patients older than 22 years old, this module is not present in the subject device. |
| Software Functionalities/ Modalities | KEOPS Balance Analyzer 3D can be used to :<br>- Provide measurements of parameters to assess the patient's sagittal and frontal balance<br>- Make a comparison between the parameters measured and those of the normal population<br>- Help surgeons to plan surgical corrections to the spinal column (levels / degree of correction), help them with diagnosis and planning surgery<br>- View the spinal column in 3D using two 2D X-ray images simultaneously | KBA3D v2.0.0 aims to achieve three objectives:<br>From two perpendicular patient's standing x-rays including patient's spine and pelvis from femoral heads to the cervical levels, provide 3D scaled representation of the femoral heads, sacral plate, and the vertebral bodies. Provide related shape and positioning parameters measurements (disc/vertebra/height/angulation), main curvatures description and global balance assessment…<br>Simulate potential effects of a spine surgery on spinopelvic alignment and provide related shape and positioning parameters calculation.<br>Visualize scaled representation of implant range (pedicle screws, interbody cages, union rods) relative to spinopelvic representation (pre-op versus realigned) to establish possible implant selection scenarios. | KBA3D v2.4.0 aims to achieve three objectives:<br>From an upright coronal and sagittal 2D X-ray that contains the patient's vertebral anatomy from femoral heads to the cervical levels (included), KBA3D creates a calibrated 3D rendering of the spine. The software provides related shape and positioning parameter measurements which include disc and vertebral height and angulation, main curvatures and global balance assessment.<br>Simulate potential effects of a spine surgery on spinopelvic alignment and provide related shape and positioning parameters calculation.<br>Visualize implant positioning relative to spinopelvic representation (pre-op versus realigned) to establish possible implant selection scenarios. | YES – Same core functionalities, differences reflect wording simplification only. |
| Image Manipulation Functions | 2D image display and basic manipulation (zoom, rotation, contrast, brightness) | 2D image display and basic manipulation (zoom, rotation, contrast, brightness) | 2D image display and basic manipulation (zoom, rotation, contrast, brightness) | YES |
| Measurement Functions | Distances, angles and diameter | Distances, angles and diameter | Distances, angles and diameter | YES |

| Characteristic | Additional Predicate Device (KBA3D v1.1.3) | Primary Predicate (KBA3D v2.0.0) | Subject Device (KBA3D v2.4.0) | Substantially Equivalent? |
|---|---|---|---|---|
| Human intervention for interpretation and manipulation of images | Yes | Yes | Yes | YES |
| Graphic Charter | S.M.A.I.O | NuVasive | S.M.A.I.O | YES - In the context of NuVasive's strategic direction following its merger with Globus Medical, SMAIO and NuVasive have announced their mutual decision to terminate their co-development efforts for surgical planning software. SMAIO consequently initiated the development of KBA3D in SMAIO colors and to remove Nuvasive material. |
| User Interface | Computer | Computer | Computer + Smartphone and Tablets (only for viewer) | YES – The difference does not impact the core functionalities (measurements and simulation), which remain performed on a computer. Mobile use is limited to viewer. |

## G. PERFORMANCE DATA

Non-clinical performance testing performed on the subject device, KBA3D v2.4.0, supports substantial equivalence to the predicate device, KBA3D v2.0.0. The following V&V testing was performed:

A. Verifications activities cover the following:

- Design input review
- Unit testing
- Software integration

B. Validations activities cover the following:

- Validation in terms of design.
- Usability testing was performed to demonstrate that the subject devices can be used safely by assessing and mitigating usability risks.
- Validation of the accuracy of clinical parameter outputs.

**KBA3D v2.4.0 software sagittal balance measurements accuracy**

| Parameter | Accuracy |
|---|---|
| Pelvic incidence | ± 0.69° |
| Pelvic tilt | ± 0.14° |
| Sacral slope | ± 0.55° |
| Barrey ratio | ± 2.03% |
| Lordosis L1S1 | ± 1.17° |
| Lordosis L4S1 / Lordosis L1S1 | ± 0.38% |
| Kyphosis T12C7 | ± 1.66° |
| SSA | ± 0.57° |

**KBA3D v2.4.0 software coronal measurements accuracy**

| Parameter | Accuracy |
|---|---|
| Curvature Angle (Cobb, °) | ± 0.65° |
| Lateral displacement (LD, pixel) | ± 1.89 pixel |
| C7 vertebral tilt in frontal plan (C7 tilt, °) | ± 0.04° |
| C7 vertebral tilt in frontal plan (C7 tilt, pixel) | ± 1.59 pixels |
| Femoral heads slope (FHS, °) | ±0.11° |
| Femoral heads slope (FHS, pixel) | ± 1.95 pixels |
| Shoulders slope (ShS, °) | ± 0.06° |
| Shoulders slope (ShS, pixel) | ± 1 pixel |
| Pelvic obliquity (PO, °) | ± 0.05° |

## H. CONCLUSIONS

Based on the information provided in this 510(k) notification, it was determined that the subject device, KBA3D v2.4.0, is substantially equivalent to the legally marketed predicate device with regards to indications for use, intended use, design, technology and performance.