S.M.A.I.O.
% Robert Poggie, Ph.D.
President
BioVera, Inc.
65 Promenade Saint Louis
Notre Dame de L'lle Perrot, Quebec J7W3J6
CANADA

May 30, 2023

Re: K223841
Trade/Device Name: KBA3D v2.0.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 2, 2023
Received: May 2, 2023

Dear Dr. 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 (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,

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)*
K223841

Device Name
KBA3D v2.0.0

Indications for Use *(Describe)*
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 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.

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.

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.

K223841

510(k) SUMMARY for K223841

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 KBA3D V2.0.0 software.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-de-L'Ile-Perrot, Québec, J7W 3J6, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone & Fax Number:	514-901-0796
Date of Submission:	May 2, 2023

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	S.M.A.I.O
Manufacturer Address:	2, Place Berthe Morisot- Parc Technologique 69800 SAINT-PRIEST, FRANCE
Registration Number:	3015383864
Contact Name:	Jean-Charles Roussouly
Title:	Operations vice-president
Device Trade Name:	KBA3D v2.0.0
Device Common Name:	Image measurement and surgery planning software
Classification Name:	Picture archiving and communications system
Classification Code:	LLZ
Classification Panel:	Radiology Devices
Regulation Number:	21 CFR sections 892.2050

C1. PRIMARY PREDICATE DEVICE

K213975	KEOPS Balance Analyzer 3D (KBA3D)

C2. PREDICATE DEVICES

K180091	UNiD Spine Analyzer, Medicrea International
K141669	Nemaris Surgimap 2.0

C3. REFERENCE DEVICE

K210574	NuVasive Pulse System

D. DEVICE DESCRIPTION

The subject device KBA3D v2.0.0 is a SaaS software solution developed by S.M.A.I.O for the medical community; it is a second, independent version of the original KBA3D cleared by FDA in K213975. The current version of the KBA3D software is v.2.0.0. The user needs and requirements of the subject device were jointly defined by S.M.A.I.O and NuVasive. The software is intended to view images, perform spine related measurements, and plan surgical procedures such as osteotomies of the spine and templating of implants (screws, cages, rods).

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:

1. From two perpendicular patient's standing x-rays including patient's spine and pelvis from the femoral heads to the cervical levels, provide 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.
2. Simulate potential effects of a spine surgery on spinopelvic alignment and provide related shape and positioning parameters calculation.
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.

The software is not intended to predict the results of surgery as S.M.A.I.O does not provide tools to carry out planning. Therefore, regarding implant sizing, positioning, and correction impacts, accuracy levels provided by S.M.A.I.O are solely based on theoretical calculations that are not correlated to the output of surgery. KBA3D V2.0.0 provides scaled and simplified representations of the screws and cages relative to the patient's spine and pelvis.

Bendini service (part of NuVasive Pulse System, K210574, reference device):

- The first request from the software to the Bendini system enables the software to retrieve the most up-to-date benders/rods configuration file.
- A second request from the software to the Bendini system enables the software to obtain specific bending instructions for the rod.

Note: The Bendini Rod Bending algorithm is intended for patients older than 22 years old. The NuVasive Bendini Web App service is comprised of an API REST web service that facilities outside clients to utilize the NuVasive Bendini Rod Bending algorithm. This algorithm is identical to the Bendini algorithm in K210574 for the NuVasive Pulse System and is hosted using the Microsoft Azure App Service. The KEOPS database manages connection to the software, patient data, and storage of data (X-rays and simulations).

E. INTENDED USE

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 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.

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.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The table below compares the technological characteristics of the KBA3D V2.0.0 to the predicate and reference devices.

	Subject Device	**Predicate Device (Primary)**	**Predicate Device**	**Predicate Device**	**Reference Device**
Feature	**KBA3D V2.0.0 K223841**	**KEOPS Balance Analyzer 3D K213975**	**Nemaris Surgimap 2.0 K141669**	**Medicrea UNiD Analyzer K180091**	**NuVasive Pulse System K210574**
Computer	PC Compatible	PC Compatible	PC Compatible	PC Compatible	PC Compatible
Operating System	Windows + MAC	Windows + MAC	Windows + MAC	Windows + MAC	Windows
Image Input	Local	Local	Local + PACS connectivity	Local	Local
Runs on Server	Yes	Yes	No	Yes	No
Osteotomy Module	Yes	Yes	Yes	Yes	No
Spine measurements	Yes	Yes	Yes	Yes	Yes
Pre-op planning	Yes	Yes	Yes	Yes	No
Screws	Yes	No	No	Yes	Yes
Cages	Yes	No	Yes	No	No
Rods	Yes	Yes	Yes	Yes	Yes (Bendini)
Database	No	No	Yes	No	No
Case sharing	No	No	Yes	No	No
Human intervention for image interpretation and manipulation	Yes	Yes	Yes	Yes	Yes

G. PERFORMANCE SUMMARY

The performance characteristics of the KBA3D V2.0.0 were tested and analyzed per the FDA's guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained on Medical Devices" and the FDA guidance document entitled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". The pre-clinical tests and results for the subject device included:

- Anatomical parameters measurements were verified via mathematical calculations. The values were compared to the parameters calculated by the KBA3D V2.0.0 software. The results showed

there was no difference in the calculations by Excel and KBA3D V2.0.0 software.

- 3D algorithm reconstruction on 2D Images were verified by comparison of Vertebral body dimensions from: (1) 3D reconstructions using the Balance Analyzer and 3D reconstructions from CT-Scan. The results showed that most of the deviations were less than 3mm and that the average was a maximum of 4.3mm (less than the maximum validation criterion of 5mm).
- Uncertainty testing studies comparing original coordinates and "worst case variation" coordinates demonstrated acceptable variations of values and validated the accuracy of the software. A deviation in distance of less than 2 pixels (px) and a deviation of not more than 2° were considered acceptable.
- Surgical Simulation was verified by applying the post treatment radiographs with the simulation algorithm in comparison with images (postop, 12 patients) by a spine surgeon. The highest value of the SSA error was 3.26% and the set of back types obtained by simulation was identical to the post-op version.
- Performance of the algorithm to position the screws was verified. A deviation < 10^{-12} mm was observed for the positioning of the entry point of the screws (less than the acceptance criterion of 0.5 mm) and a deviation < 0.3° was observed for the angulation of each screw in the vertebra ((less than the acceptance criterion of 0.5°)
- Performance of the algorithm to position the cage was verified. A deviation < 0.4mm offset was observed between the height of the café and the disc space (less than the acceptance criterion of 0.5 mm) and a deviation < 10^{-12}° was observed for the angulation between the two vertebrae and the angulation given by the cage (less than the acceptance criterion of 0.5°)
- Formative and summative studies demonstrated the safety and usability intuitiveness of the KBA3D V2.0.0 software. Intuitive use was confirmed and the users successfully performed measurements and 3D reconstruction that simulated surgery.

Software validation and performance testing of the KBA3D V2.0.0 consisted of verification and validation activities using the following guidelines and standards throughout the software development process:

EN ISO 14971:2019	Application of risk management to medical devices
IEC 62304:2006	Medical device software - Software life cycle processes
EN 62366-1:2015/A1:2020	Medical Device Part I – Application of the Usability Engineering to Medical Devices
IEC 82304-1:2016	Health Software – Part I General Requirements For Products Safety
FDA Guidance for Industry and FDA Staff	Guidance for the content of premarket submissions for software contained in medical devices (May 11, 2005)

The software for the KBA3D V2.0.0 is of Moderate level of concern.

H. CONCLUSIONS

The KBA3D v2.0.0 is substantially equivalent to the primary predicate device KEOPS Balance Analyzer 3D (K213975) which we relied upon in determining substantial equivalence for the subject device for similarities in indications for use, design, technological characteristics, performance data, and user interface presented in this 510(k) notification.