S.M.A.I.O
% Robert A. Poggie, Ph.D.
President
BioVera, Inc.
65 Promenade Saint Louis
Notre Dame de Llle Perrot, Quebec J7V7P2
CANADA

May 6, 2022

Re: K213975
Trade/Device Name: KEOPS Balance Analyzer 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 1, 2022
Received: April 5, 2022

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 (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,

For

Thalia T. Mills, Ph.D.
Director
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)*
K213975

Device Name
KEOPS Balance Analyzer 3D

Indications for Use *(Describe)*
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.

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.

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510(k) SUMMARY for K213975

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, NDIP, Québec, J7V 7P2, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone & Fax Number:	514-901-0796
Date of Submission:	May 3, 2022

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:	KEOPS Balance Analyzer 3D (KBA3D)
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

K141669	SURGIMAP, NEMARIS INC

C2. PREDICATE DEVICE

K180091	UNiD Spine Analyzer, Medicrea International

D. DEVICE DESCRIPTION

The KEOPS Balance Analyzer 3D (KBA3D) is a software solution developed for the medical community. It is intended to view images and perform spine related measurements and plan surgical procedures. The image formats supported include standards such as jpeg, tiff, png, and DICOM file types. Images can be stored in the KEOPS database and measurements made using generic measuring and surgical tools within overlays of the images. The KEOPS Balance Analyzer 3D offers the ability to plan spine surgical procedures such as osteotomies of the spine and templating implants (rods). Keops Balance Analyzer 3D is web-based software.

E. 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 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.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The table below compares the technological characteristics of the KEOPS Balance Analyzer 3D subject device to the Nemaris and Medicrea predicate devices.

Feature	**Keops Balance Analyzer 3D (KBA3D) K # TBD**	**Nemaris Surgimap 2.0 K141669**	**Medicrea UNiD Spine Analyzer K180091**
Computer	PC Compatible	PC Compatible	PC Compatible
Operating System	Windows + MAC	Windows + MAC	Windows + MAC
Image Input	Local	Local + PACS connectivity	Local
Runs on Server	Yes	No	Yes
Osteotomy Module	Yes	Yes	Yes
Spine measurements	Yes	Yes	Yes
Pre-operative planning	Yes	Yes	Yes
Database	No	Yes	No
Case sharing	No	Yes	No
Human Intervention for interpretation and manipulation of images	Yes	Yes	Yes
Web content	Yes	Yes	Yes

The subject and predicate devices possess similar or the same technological, performance, and user-interface characteristics that are intended to aid health care professionals in the pre-operative planning of spine surgery. The minor differences in features present no new risks. The similarity of the technological features indicates the subject and predicate devices are substantially equivalent.

G. PERFORMANCE SUMMARY

The performance characteristics of the Keops Balance Analyzer 3D 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 non-clinical tests performed with the subject included:

- Anatomical parameters measurements were verified via mathematical calculations.

- 3D algorithm reconstruction on 2D Images (Profile and Face) were verified by comparing vertebral body dimensions from the features 'Balance Analyzer 3D reconstruction' and '3D reconstruction CT-Scan'.
- Accuracy and precision testing were conducted to demonstrate the performance of the software.
- Surgical Simulation was verified by applying the post treatment radiographs with the simulation algorithm with comparison post operative images.
- A study was conducted with fifteen spine surgeons to validate the usability of the KBA3D software.

The results of the non-clinical performance testing showed:

- Comparison of original and "worst case variation" coordinates demonstrated acceptable variations of values and validated the accuracy of the software in measuring anatomical parameters.
- Data point acquisition was determined to be repeatable and reliable based on measurements showing location of the barycenter to be within the acceptance criteria of 3 pixels (or less).
- Calculation of spino-pelvic parameters showed no difference in results between the KBA3D software and manual calculations using MS Excel.
- The reliability of the KBA3D surgical planning and simulation algorithm was demonstrated by comparing the planned corrections by the software to the actual corrections obtained from post-operative radiographic images. The acceptance criteria were met.
- The reliability of KBA3D 2D3D reconstruction algorithm was validated by comparing 3D models from CT scans to 3D reconstructions from the KBA3D software from X-ray images; the results met the acceptance criteria of an allowable maximum deviation of 5mm (which is 10% of the average dimension of a vertebral body).
- The usability of the software was validated for the process of acquisition and intuitiveness of use by orthopaedic spine surgeons using the software for the first time. The results showed no measurable, clinically relevant differences between the user groups.

In addition, Software validation and performance testing of the KEOPS Balance Analyzer 3D consisted of verification and validation activities using the following guidelines and standards throughout the software development process:

EN ISO 14971	Application of risk management to medical devices
IEC 62304	Medical device software - Software life cycle processes
ANSI/IEEE Standard 829-2008	IEEE Standard for Software and System Test Documentation
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 KEOPS Balance Analyzer 3D is of moderate level of concern.

H. CONCLUSIONS

The KEOPS Balance Analyzer 3D is substantially equivalent to the identified predicate devices based on similarities in indications for use, design, technological characteristics, performance data, and user interface presented in this 510(k) notification.