December 9, 2022

3D-Shaper Medical S.L
% Ludovic Humbert
CEO
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Barcelona, Barcelona 08036
SPAIN

Re: K220822
Trade/Device Name: 3D-SHAPER
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: Class II
Product Code: KGI
Dated: November 4, 2022
Received: November 4, 2022

Dear Ludovic Humbert:

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,

Lu Jiang
2022.12.09
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Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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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)*
K220822

Device Name
3D-SHAPER

Indications for Use *(Describe)*
3D-SHAPER uses data from conventional Dual Energy X-Ray Absorptiometry (DXA) scans to measure the distribution of bone mineral mass at specific cross sections or regions of the hip and allows the physician to estimate structural properties of the hip, such as CSA, CSMI, Z, Buckling Ratio, cortical sBMD, trabecular vBMD and integral vBMD.

3D-SHAPER is indicated to be used by qualified medical professionals to assist healthcare professionals in the bone health evaluation & changes, and cannot fully substitute their clinical judgement.

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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1 General Information

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements detailed in 21 CFR 807.92.

The assigned 510(k) number is: K220822

SUBMITTER NAME: 3D-SHAPER MEDICAL S.L.

SUBMITTER ADDRESS: C/ Paris 179, 2º-2º

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DATE PREPARED: March, 7, 2022

DEVICE TRADE NAME: 3D-SHAPER

COMMON NAME: 3D Analysis software for Bone Densitometers

DEVICE CLASS: Class II

REGULATION NUMBER 892.1170

REGULATION NAME Bone Densitometer

PRODUCT CODE: KGI

PREDICATE DEVICE(S): HIP STRUCTURAL ANALYSIS SOFTWARE OPTION FOR THE HOLOGIC QDR X-RAY BONE DENSITOMETERS (K061561)

1 Description of the device and its intended use

3D-SHAPER is a software reconstructing in 3D, the shape and bone mineral density from 2D DXA images. The software incorporates a DXA-based 3D reconstruction algorithm and measures the distribution of bone mineral mass at specific cross sections or regions of the hip. It provides physicians with estimates of the structural properties of the hip, such as densities or geometrical parameters. The software is not suitable for use with paediatric patients or for subjects with hip prosthesis such as total hip replacement prosthesis, hip resurfacing prosthesis or an osteosynthesis system, since the software has not been tested against these conditions. 3D-SHAPER is indicated to be used by qualified medical professionals to assist healthcare professionals in the bone health evaluation & changes, and cannot fully substitute their clinical judgement.

The 3D-SHAPER® measurements include:

Cortical surface Bone Mineral Density (Cortical sBMD, mg/cm^2)

Trabecular volumetric Bone Mineral Density (Trabecular vBMD, mg/cm^3)

Integral volumetric Bone Mineral Density (Integral vBMD, mg/cm^3), the integral compartment being the union of the cortical and trabecular compartments.

Hip structural measurements: Cross-Sectional Area (CSA, in cm^2), Cross-Sectional Moment of Inertia (CSMI, in cm^4), section modulus (Z, in cm^3) and buckling Ratio (BR).

Cortical sBMD, trabecular VBMD and integral vBMD are calculated at the total femur. CSA, CSMI, Z and BR are calculated in cross-sections at the neck, intertrochanteric region and lower shaft.

INTENDED USE:

As established in the Indications for Use Statement :

> 3D-SHAPER uses data from conventional Dual Energy X-Ray Absorptiometry (DXA) scans to measure the distribution of bone mineral mass at specific cross sections or regions of the hip and allows the physician to estimate structural properties of the hip, such as CSA, CSMI, Z, Buckling Ratio, cortical sBMD, trabecular vBMD and integral vBMD.
>
> 3D-SHAPER is indicated to be used by qualified medical professionals to assist healthcare professionals in the bone health evaluation & changes, and cannot fully substitute their clinical judgement.

2 Summary of Comparison with Predicate Device

Characteristics and features of the 3D-SHAPER software application have been compared to the features of the chosen, previously cleared, predicate device. The following predicate device was selected due to the similarities in application features, intended use and indications for use.

510(k) Number	Product	Manufacturer
K061561	HIP STRUCTURAL ANALYSIS SOFTWARE OPTION FOR THE HOLOGIC QDR X-RAY BONE DENSITOMETERS	HOLOGIC, INC.

***Table 1**. Information about Predicate Device*

Comparison of the proposed device with the predicate device is summarized in the following table:

Elements of Comparison	New Device 3D-SHAPER (3D-SHAPER MEDICAL S.L)	Predicate Device Hip Structural Analysis (HSA) Software Option for the Hologic QDR X-Ray Bone Densitometers (Hologic, Inc)	Discussion
Regulatory Data			
Regulatory Class	Class II	Class II	Identical
Classification name	Bone Densitometer	Bone Densitometer	Identical
Regulation Number	21 CFR 892.1170	21 CFR 892.1170	Identical
Product Code	KGI	KGI	Identical
FDA Clearance	-	510(k) cleared: K061561	-
Use			

Elements of Comparison	New Device 3D-SHAPER (3D-SHAPER MEDICAL S.L)	Predicate Device Hip Structural Analysis (HSA) Software Option for the Hologic QDR X-Ray Bone Densitometers (Hologic, Inc)	Discussion
Indication for Use / Intended Use	3D-SHAPER uses data from conventional Dual Energy X-Ray Absorptiometry (DXA) scans to measure the distribution of bone mineral mass at specific cross sections or regions of the hip and allows the physician to estimate structural properties of the hip, such as CSA, CSMI, Z, Buckling Ratio, cortical sBMD, trabecular vBMD and integral vBMD. 3D-SHAPER is indicated to be used by qualified medical professionals to assist healthcare professionals in the bone health evaluation & changes, and cannot fully substitute their clinical judgement.	The Hip Structure Analysis (HSA®) for QDR X-ray Bone Densitometers uses data from conventional Dual Energy X-ray Absorptiometry (DXA) scans to measure the distribution of bone mineral mass at specific cross sections of the hip and allows the physician to estimate structural properties of the hip, such as CSA, CSMI, Z and Buckling Ratio.	Similar to Predicate device
Technical characteristics			
General description	Is a software solution to estimate bone mineral distribution and structural properties of the hip.	Is a software solution to estimate bone mineral distribution and structural properties of the hip.	identical
Mode of action	Software Solution	Software Solution	Identical
Operating System	Windows	Windows	Identical

Elements of Comparison	New Device 3D-SHAPER (3D-SHAPER MEDICAL S.L)	Predicate Device Hip Structural Analysis (HSA) Software Option for the Hologic QDR X-Ray Bone Densitometers (Hologic, Inc)	Discussion
Principles of operation	Analysis of DXA images	Analysis of DXA images	Identical
User Interface	Mouse, Keyboard	Mouse, Keyboard	Identical
Target Population	Patients needing a bone health assessment.	Patients needing a bone health assessment.	Identical
Anatomical sites	Hip	Hip	Identical
Conditions of use	It is intended for exclusive use by professional users. The software is intended to assist healthcare professionals in the bone health evaluation and cannot fully substitute their clinical judgement.	It is intended for exclusive use by professional users. The software is intended to assist healthcare professionals in the bone health evaluation and cannot fully substitute their clinical judgement.	Identical
Images supported	Dual Energy X-ray Absorptiometry (DXA) scans from Bone Densitometers	Dual Energy X-ray Absorptiometry (DXA) scans from Bone Densitometers	Identical
Image Features			
Image assessment	By visualization and analysis of the images	By visualization and analysis of the images	Identical
Image display and manipulation	- 2D review - Pan/zoom; magnify; maximize and minimize; scroll through	- 2D review - Adjust window level, contrast and brightness.	Similar to predicate device

Elements of Comparison	New Device 3D-SHAPER (3D-SHAPER MEDICAL S.L)	Predicate Device Hip Structural Analysis (HSA) Software Option for the Hologic QDR X-Ray Bone Densitometers (Hologic, Inc)	Discussion
	slice stack; adjust window level, contrast and brightness.		
Result visualization	- Numerical - Graph - 2D view - 3D view	- Numerical - Graph - 2D view	Similar to predicate device
Export capabilities	- Snapshots as PNG - Numerical data as CSV file - Study data as an internal file format - 3D-Shaper analysis as a proprietary file format - Report	- Numerical data as a database file - Study data as an internal file format - DXA scan as a proprietary file format - Report	Similar to predicate device
Performing Bone Analysis			
	Measure the distribution of bone mineral mass from a 3D image of the hip and allow the physician to estimate structural properties of the hip, such as CSA, CSMI, Z, Buckling Ratio, volumetric bone mineral densities and surface bone mineral density.	Measure the distribution of bone mineral mass from a 2D image of the hip and allows the physician to estimate structural properties of the hip, such as CSA, CSMI, Z and Buckling Ratio.	Similar to predicate device

Table 2. *Comparison of technological characteristics and features - proposed and Predicate device*

3D-SHAPER software has the same indications for use and similar technological characteristics as the predicate device. Additionally, 3D-SHAPER and its predicate device are a software option to the Bone Densitometer equipment and as such, has the same Regulation Number & Product Code as the predicate device. Both devices proposed the same functionality in terms of Image display and manipulation, results visualization and export capabilities.

A correlation study has been performed to compare structural properties of the hip (such as CSA, CSMI, Z, Buckling Ratio) as well as volumetric bone mineral densities and surface bone mineral density obtained by 3D-SHAPER software and its predicate device. This study involved 740 men and women (94% women) aged 17 to 92 years old that were analysed using both 3D-SHAPER software and its predicate device. Very strong correlation coefficients ($r \geq 0.9$) were found between 3D-SHAPER and predicate device measurements for Integral vBMD, Trabecular vBMD, Cortical sBMD, CSA, CSMI and Z. Likewise, strong correlation coefficients ($r \geq 0.7$) were found between 3D-SHAPER and predicate device measurements for Buckling Ratio.

Based on this analysis, 3D-SHAPER Medical believes that the new device is considered substantially equivalent to the predicate device in terms of safety or effectiveness.

3 Design and Development of Device

Design and development included identification, evaluation and control of potential hazards as per standards ISO 14971 “Medical devices – Application of risk management to medical devices”. The software development life-cycle included integration, verification and validation testing and was successfully completed following standard IEC 62304 “Medical device software – Software life-cycle processes” and IEC 82304 “Health software - Part 1: General requirements for product safety”.

Additionally, 3D-SHAPER was designed, developed, tested, verified and validated according to documented procedures and specific protocols in line with the following FDA guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – May 11, 2005
- Guidance for Off-The-Shelf Software Use in Medical Devices – September 27, 2019
- Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software – January 14, 2005
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff – January 11, 2002.
- Guidance for Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices – September 6, 2017

- Guidance for Management of Cybersecurity in Medical Devices – October 18, 2018

4 Performance Bench Testing

The Performance Bench testing showed that 3D-SHAPER computing time was lower than two minutes and 30 seconds and software convergence superior to 95%. 3D-SHAPER provides accurate subject-specific models of the femoral shape and measurements compared to Quantitative Computed Tomography (QCT). Very strong correlations (r) were found between 3D measurements obtained using 3D-SHAPER and QCT for integral vBMD (r=0.96), Cortical sBMD (r=0.95), Trabecular vBMD (r=0.93), CSA ($r \geq 0.95$), CSMI ($r \geq 0.92$) and Z ($r \geq 0.91$) while strong correlations were found for BR ($r \geq 0.71$). 3D-SHAPER provides precise 3D measurements that can be used to monitor bone changes over time. 3D-SHAPER supports DXA files obtained from GE and Hologic DXA Scanners.

5 Clinical Testing

Safety and performance of the proposed software is based on the software development life-cycle and bench testing. Design & Verification did not require clinical testing.

6 Summary Conclusions

Device description, intended use and indications for use for 3D-SHAPER have been identified and established. Results obtained from all performance testing, show fulfilment of the device design specifications, where applicable in accordance with the reference standards.

Specific characteristics, intended use and indications for use of the different system components have been compared with corresponding predicate devices. Results of the comparison indicate the presence of minor differences that we believe do not affect safety and performance.

We therefore believe that all issues regarding safety and performance of the proposed device have been successfully addressed and that the similarity of the device with the established predicates strongly supports the determination of substantial equivalence.