



September 5, 2025

3d-shaper Medical S.1  
% Ludovic Humbert  
President  
Rambla Catalunya, 53, 4-H  
BARCELONA, 08007  
SPAIN

Re: K251022

Trade/Device Name: 3D-SHAPER  
Regulation Number: 21 CFR 892.1170  
Regulation Name: Bone Densitometer  
Regulatory Class: Class II  
Product Code: KGI  
Dated: August 4, 2025  
Received: August 4, 2025

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A large, light blue watermark of the FDA logo is visible in the background. Overlaid on this watermark is the signature "Lu Jiang" in a black, cursive script.

Lu Jiang, Ph.D.  
Assistant Director  
Diagnostic X-Ray Systems Team  
DHT8B: Division of Radiologic 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

510(k) Number (if known)

K251022

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 the hip and allows the physician to estimate structural properties of the hip, such as cortical sBMD, trabecular vBMD and integral vBMD.

These values can then be compared to an adult reference population at the sole discretion of the physician. The results can assist the physician in the assessment of relative fracture risk.

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.

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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: K251022

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

**SUBMITTER ADDRESS:** Rambla Catalunya 53, 4-H  
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BARCELONA  
SPAIN

**CONTACT:** Ludovic Humbert

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**DATE PREPARED:** March, 31, 2025

**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):** 3D-SHAPER (K220822)

GEHC DXA Bone Densitometers with enCORE version 18 (K191112)

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## 2 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 the hip. It provides physicians with estimates of the structural properties of the hip, such as cortical sBMD, trabecular vBMD and integral vBMD. The software is not suitable for use with pediatric 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 the following parameters calculated at the total femur:

- Cortical surface Bone Mineral Density (Cortical sBMD, mg/cm<sup>2</sup>)
- Trabecular volumetric Bone Mineral Density (Trabecular vBMD, mg/cm<sup>3</sup>)
- Integral volumetric Bone Mineral Density (Integral vBMD, mg/cm<sup>3</sup>), the integral compartment being the union of the cortical and trabecular compartments.

### INTENDED USE / INDICATIONS FOR 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 the hip and allows the physician to estimate structural properties of the hip, such as cortical sBMD, trabecular vBMD and integral vBMD.

These values can then be compared to an adult reference population at the sole discretion of the physician. The results can assist the physician in the assessment of relative fracture risk.

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.

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### 3 Comparison with the predicate devices

For the purpose of determining substantial equivalence, two Predicate Devices were used (Table 1); it should be noted that the Primary Predicate is the previously cleared version of the same 3D-Shaper software.

*Table 1. Predicate Devices*

	510(k) Number	Product Names	Manufacturer
Primary Predicate	K220822	3D-SHAPER version 2.11	3D-SHAPER MEDICAL S.L.
Secondary Predicate	K191112	GEHC DXA Bone Densitometers with enCORE version 18	GE Healthcare

Table 2 compares the Intended use / Indications for use, technological characteristics and features of the Subject Device with those of the Predicate Devices.

*Table 2. Comparison of Intended use / Indications for use, technological characteristics and features of the Subject Device and the Predicate Devices.*

Product name	Subject Device 3D-SHAPER version 2.14	Primary Predicate 3D-SHAPER version 2.11	Secondary Predicate GEHC DXA Bone Densitometers with enCORE version 18	Discussion
Regulatory Class	Class II	Class II	Class II	Identical
Classification name	Bone Densitometer	Bone Densitometer	Bone Densitometer	Identical
Regulation Number	21 CFR 892.1170	21 CFR 892.1170	21 CFR 892.1170	Identical
Product Code	KGI	KGI	KGI	Identical
510(k)	-	K220822	K191112	-
Intended use / Indications for use	3D-SHAPER uses data from conventional Dual Energy X-Ray Absorptiometry (DXA) scans to measure the distribution of bone mineral mass at the hip and allows the physician to estimate structural properties of the hip, such as cortical sBMD, trabecular vBMD and integral vBMD.	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,	Provides an estimate of bone mineral density at various anatomical sites (Spine, Femur, Total Body, and Forearm).	Similar

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<b>Product name</b>	<b>Subject Device</b> 3D-SHAPER version 2.14	<b>Primary Predicate</b> 3D-SHAPER version 2.11	<b>Secondary Predicate</b> GEHC DXA Bone Densitometers with enCORE version 18	<b>Discussion</b>
	<p>These values can then be compared to an adult reference population at the sole discretion of the physician.</p> <p>The results can assist the physician in the assessment of relative fracture risk.</p> <p>-</p> <p>-</p>	<p>cortical sBMD, trabecular vBMD and integral vBMD.</p> <p>-</p> <p>-</p> <p>-</p>	<p>These values can then be compared to an adult reference population at the sole discretion of the physician.</p> <p>Provides an assessment of relative fracture risk based on the patient's T-score value using the categories of fracture risk defined by the World Health Organization (WHO).</p> <p>Provides an assessment of 10-year fracture risk using WHO FRAX model.</p> <p>Provides a standardized bone density report using data from the densitometer and physician-generated assessments based on the patient's demographics, which can assist the physician in communicating scan results to the patient and the patient's referring physician.</p>	<p>Identical</p> <p>Similar</p> <p>Not included in the Subject Device</p> <p>Not included in the Subject Device's indications for use. However, Subject Device provides similar reporting functionality.</p>
	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.	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.	-	Identical
Measurements	<p>Cortical sBMD, trabecular vBMD and integral vBMD</p> <p>sBMD/vBMD T-score and Z-score</p>	<p>cortical sBMD, trabecular vBMD and integral vBMD</p> <p>CSA, CSMI, Z, Buckling Ratio</p>	<p>BMD</p> <p>BMD T-score and Z-score</p>	Similar

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<b>Product name</b>	<b>Subject Device</b> 3D-SHAPER version 2.14	<b>Primary Predicate</b> 3D-SHAPER version 2.11	<b>Secondary Predicate</b> GEHC DXA Bone Densitometers with enCORE version 18	<b>Discussion</b>
	Categories: normal, low, or very low density		WHO Categories: normal, low bone mass, or Osteoporosis	
Anatomical sites	Hip	Hip	Hip, Spine, Total Body, and Forearm	Similar
Reporting	sBMD/vBMD values  Graph showing the changes over time  Graph showing the values against age-related reference data and categories	sBMD/vBMD values  Graph showing the changes over time	BMD values  Graph showing the changes over time  Graph showing the values against age-related reference data and categories	Similar
Mode of action	Software Solution	Software Solution	Software Solution	Identical
Operating System	Windows	Windows	Windows	Identical
Principles of operation	Analysis of DXA images	Analysis of DXA images	Analysis of DXA images	Identical
User Interface	Mouse, Keyboard	Mouse, Keyboard	Mouse, Keyboard	Identical
Target Population	Subjects needing a bone health assessment.	Subjects needing a bone health assessment.	Subjects needing a bone health assessment.	Identical
Conditions of use	It is intended for exclusive use by healthcare professionals.  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 healthcare professionals.  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 healthcare professionals.  The software is intended to assist healthcare professionals in the bone health evaluation and cannot fully substitute their clinical judgement.	Identical
Input Images supported	DXA scans	DXA scans	DXA scans	Identical
Image assessment	By visualization and analysis of the images	By visualization and analysis of the images	By visualization and analysis of the images	Identical

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<b>Product name</b>	<b>Subject Device 3D-SHAPER version 2.14</b>	<b>Primary Predicate 3D-SHAPER version 2.11</b>	<b>Secondary Predicate GEHC DXA Bone Densitometers with enCORE version 18</b>	<b>Discussion</b>
Image display and manipulation	<ul style="list-style-type: none"> <li>- 2D review</li> <li>- Mask manipulation (brush &amp; points)</li> <li>- Pan/zoom; reset; maximize and minimize; contrast, brightness; adjust window level.</li> <li>- Scroll through slice stack</li> </ul>	<ul style="list-style-type: none"> <li>- 2D review</li> <li>- Mask manipulation (brush &amp; points)</li> <li>- Pan/zoom; reset; maximize and minimize; contrast, brightness; adjust window level.</li> <li>- Scroll through slice stack</li> </ul>	<ul style="list-style-type: none"> <li>- 2D review</li> <li>- ROI adjustment</li> <li>- Mask manipulation (brush &amp; points)</li> <li>- Pan/zoom; reset; maximize and minimize; contrast and brightness; sharpness.</li> </ul>	Identical to Primary Predicate & similar to Secondary Predicate
Result visualization	<ul style="list-style-type: none"> <li>- Numerical</li> <li>- Graph (with reference data &amp; categories)</li> <li>- 2D view</li> <li>- 3D view</li> </ul>	<ul style="list-style-type: none"> <li>- Numerical</li> <li>- Graph</li> <li>- 2D view</li> <li>- 3D view</li> </ul>	<ul style="list-style-type: none"> <li>- Numerical</li> <li>- Graph (with reference data &amp; categories)</li> <li>- 2D view</li> </ul>	Similar
Export capabilities	<ul style="list-style-type: none"> <li>- Snapshots as PNG</li> <li>- Numerical data as a comma-separated value (CSV) file</li> <li>- Study data as an internal file format</li> <li>- 3D-Shaper analysis as a proprietary file format</li> <li>- Report</li> <li>- DICOM Connectivity</li> </ul>	<ul style="list-style-type: none"> <li>- Snapshots as PNG</li> <li>- Numerical data as a comma-separated value (CSV) file</li> <li>- Study data as an internal file format</li> <li>- 3D-Shaper analysis as a proprietary file format</li> <li>- Report</li> </ul>	<ul style="list-style-type: none"> <li>- Snapshot as JPG</li> <li>- Numerical data as a tab-delimited text file</li> <li>- DXA scan as a proprietary file format</li> <li>- Report</li> <li>- DICOM Connectivity</li> </ul>	Similar

The substantial equivalence between the Subject Device and the Predicate Devices was established based on the comparison outlined in Table 2 and the discussion on intended use, measurements, technological characteristics and features.

After evaluating the modifications, we conclude that the changes in the indication for use to the subject device do not impact its safety and effectiveness.

The changes in the indications for use, compared to the predicate device, primarily involve the exclusion of specific parameters (CSA, CSMI, Z, and Buckling Ratio). These parameters were not included in the 3D-SHAPER clinical report and were not utilized for clinical decision-making; therefore, their removal does not affect potential users of 3D-SHAPER.

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Additionally, the inclusion of reference data for an adult population in the indications for use provides support for interpreting 3D-SHAPER measurements. These reference values align with NHANES III, the recommended reference standard for DXA measurements. This modification does not affect the safety and effectiveness of the device, as these values serve only as supplementary information to assist physicians in data interpretation.

The addition of relative fracture risk values enables identical reporting features, allowing comparisons to reference data and categories. This includes graphical representations against age-related reference data. These changes do not compromise the device’s safety and effectiveness, as clinical studies have demonstrated the association between 3D-SHAPER measurements and fracture risk.

In conclusion, while the indications for use of the subject device differ from those of the legally marketed predicate device, these differences are not critical to the intended use. The modifications introduced do not compromise, alter, or negatively impact the safety and effectiveness of the 3D-SHAPER device.

## 4 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:

- Content of Premarket Submissions for Device Software functions – June 14, 2023
- Off-The-Shelf Software Use in Medical Devices – August 11, 2023
- 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
- Postmarket Management of Cybersecurity in Medical Devices – December 28, 2016
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – September 27, 2023
- Best Practices for selecting a Predicate Device Support a Premarket Notification [510(k)] submission. Draft Guidance –September 7, 2023

## 5 Performance Bench Testing

Some of the software aspects assessed in the Performance Bench Testing of 3D-SHAPER version 2.14 were already evaluated in the previous version, 3D-SHAPER 2.11 (K220822), which serves as the

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Primary Predicate in this submission. Specifically, computing time, convergence, accuracy, precision, compatibility with DXA scanners, and inter-scanner variability were part of the Performance Bench Testing for version 2.11 and were reevaluated using the updated 2.14 version of 3D-SHAPER. The performance of the updated 3D-SHAPER version 2.14 was found to be equivalent to that of version 2.11.

3D-SHAPER version 2.14 includes age-related reference data that can be used to support the interpretation of the output measurements. The reference data include thresholds that can be used to categorize the cortical and trabecular bone density as normal, low or very low. The methodology employed to build the reference data is described in the Performance Bench Testing. A comparison with NHANES reference data was performed. The age-related reference data were tested using independent datasets from Spain and the U.S. The agreement between the classification performed using the BMD T-score, as determined by the Secondary Predicate, and the classification performed using the 3D-SHAPER measurements was 75% or higher. 3D-SHAPER measurements-based categories were found to be consistent with BMD T-score-based categories from the Secondary Predicate.

The Performance Bench Testing includes a review of six clinical studies that used 3D-SHAPER to assess its association with fracture. A decrease in 3D-SHAPER Integral vBMD, Trabecular vBMD or Cortical sBMD was found to be associated with an increased risk of fracture. The 3D-SHAPER measurements showed a similar association with fracture risk compared to BMD, which is the main measurement provided by the Secondary Predicate. 3D-SHAPER measurements can be used to support physicians in fracture risk assessment.

These studies demonstrate that the Subject Device and the Primary and Secondary Predicates exhibit similar clinical outcomes and performance characteristics, thereby supporting the conclusion that the Subject Device is as safe and effective as the Primary and Secondary Predicates.

## 6 Conclusions

3D-SHAPER version 2.14 and the Predicate Devices have similar indications for use / intended use, similar design and technological characteristics, similar functional specifications and performance.

We consider that the safety and effectiveness of Subject Device, 3D-SHAPER version 2.14, are comparable to the Predicate Devices and hence, substantial equivalence of 3D-SHAPER version 2.14 with the legally marketed Predicate Devices has been established.