July 17, 2025

GENORAY Co., Ltd.
Jiyeon Choi
Manager
60, Dunchon-daero 541beon-gil
Jungwon-gu
Seongnam-si, Gyeonggi-do 13212
Korea, South

Re: K243420
Trade/Device Name: HESTIA
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: June 10, 2025
Received: June 10, 2025

Dear Jiyeon Choi:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
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DHT8C: Division of Radiological
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243420

Device Name
HESTIA

Indications for Use *(Describe)*
HESTIA is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. HESTIA is intended to be used in the same clinical applications as traditional film/screen systems.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K243420

510(k) Summary

Prepared on: 2025-07-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	GENORAY Co., Ltd.
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Applicant Contact	Ms. INYOUNG KIM
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	HESTIA
Common Name	Full-field digital mammography system
Classification Name	Full Field Digital, System, X-Ray, Mammographic
Regulation Number	892.1715
Product Code(s)	MUE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K212873	Aspire Cristalle	MUE

Device Description Summary

21 CFR 807.92(a)(4)

HESTIA is a Full-Field Digital Mammography (FFDM) System for screening, diagnostic on standing or seated patients. The system consists of a control unit with x-ray generator, a compression device(C-arm) with tube housing assembly, and X-ray tube stand, including detector and a console with an operation panel. The HESTIA comes with a variety of compression plates for diagnostic adjunct procedures.

The system is mainly used in internal medicine, examination centers, obstetrics and gynecology, women's medicine, breast surgery, and imaging. Mammography X-rays are used to obtain diagnostic images of the breast's internal structure to diagnose changes more accurately in breast tissue or potential signs of breast cancer, such as micro-calcification or tumors.

HESTIA has three output control mode, Manual mode, Semi-auto mode, and Auto mode.

It is customized and dedicated acquisition workstation and can PACS accessibility with full DICOM capability.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

HESTIA is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. HESTIA is intended to be used in the same clinical applications as traditional film/screen systems.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for HESTIA are the same as for the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

HESTIA has identical indications for use and technical characteristic as its predicate device.

The charactertics of HESTIA is identical to those of the predicate device regarding indication for use, patient population, exposure mode, x-ray focal spot size, target material, target angle, kV range, Type of geometry, Software Controlled functions(AEC Calculation, DICOM)

The criteria below are similar or different. but, There is no significant difference between the HESTIA and the predicate device that would adversely affect the use of the product.
- Breast Compression system
- Added filter is similar to that of predicate device, but provides more option than predicate device. Inherent filtration is similar to that of predicate device, but has a lower than predicate device.
- Nominal maximum output power, mAs range, SID, Source to breast support distance are similar to that of predicate device, these values are higher than predicate device or at a value of similar level.
- Sensor material of the detector is different for the predicate device and subject device, but the active area and active array are similar.
- Operating system is similar to that of predicate device.

Even though the predicate device and the subject device differ, the differences are not critical in terms of the diagnostic purposes because the clinical image evaluation demonstrate that the subject devices are substantially equivalent to the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

[Summary of Non-Clinical data]
To demonstrate safety and effectiveness of HESTIA and to show substantial equivalence to the predicate device, HESTIA completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The HESTIA passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

HESTIA has been tested by 3rd party Nationally Recognized Testing Laboratories to be in compliance with the following International Standards:

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-3 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-45 Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
IEC 62304 Medical device software - Software life cycle processes
ISO 14971 Medical Devices - Application of Risk Management to Medical Devices.

And Physical laboratory testing in accordance with the Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System issued on April 4, 2012 (Section 9 Clinical Image Evaluation) was conducted with the HESTIA. For all tests, the proposed device demonstrated substantial equivalence to the predicate device.

Summary of physically laboratory testing results:
1. Sensitometric response
2. Spatial resolution
3. Noise analysis
4. Signal-to-Noise Ratio Transfer-DQE
5. Dynamic range
6. Repeated exposures Test (Lag Effect)
7. AEC Performance (CNR and SRN)
8. Phantom test - ACR Map
9. Phantom test - CDMAM

10. Patient radiation dose - Mean Glandular Dose

[Summary of Clinical data]
A clinical image evaluation in accordance with the Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System issued on April 4, 2012 (Section 9 Clinical Image Evaluation) was conducted with the HESTIA and determined that the images, reviewed by MQSA qualified expert radiologists, were of sufficiently acceptable quality for mammographic usage and that the images are substantially equivalent to those from predicate device.

[Conclusion]
HESTIA has the same intended use as the predicate device. Any minor differences in the technological characteristics of the subject device when compared to the predicate device have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, HESTIA has been determined to be substantially equivalent to predicate device.