



August 27, 2025

Durr Dental SE
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES, FL 34114

Re: K250947

Trade/Device Name: VistaSoft 4.0 and VisionX 4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: April 14, 2025
Received: July 28, 2025

Dear Daniel Kamm:

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,



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)

K250947

Device Name

VistaSoft 4.0 and VisionX 4.0

Indications for Use (Describe)

VistaSoft 4.0 and VisionX 4.0 imaging software is an image management system that allows dentists to acquire, display, edit, view, store, print, and distribute medical images. VisionX 4.0 / VistaSoft 4.0 runs on user provided PC compatible computers and utilize previously cleared digital image capture devices for image acquisition.

The software must only be used by authorized healthcare professionals in dental areas for the following tasks:

- Filter optimization of the display of 2D and 3D images for improved diagnosis
- Acquisition, storage, management, display, analysis, editing and supporting diagnosis of digital/digitised 2D and 3D images and videos
- Forwarding of images and additional data to external software (third-party software)

The software is not intended for mammography use.

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	VistaSoft 4.0 and VisionX 4.0
Common Name	Medical image management and processing system
Classification Name	Medical image management and processing system.
Regulation Number	892.2050
Product Code(s)	QIH

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213326	VisionX 3.0	LLZ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

VisionX 4.0 / VistaSoft 4.0 imaging software is an image management system that allows dentists to acquire, display, edit, view, store, print, and distribute medical images. VisionX 4.0 / VistaSoft 4.0 runs on user provided PC compatible computers and utilize previously cleared digital image capture devices for image acquisition. Additional information: The software is intended for the viewing and diagnosis of image data in relation to dental issues. Its proper use is documented in the operating instructions of the corresponding image-generating systems. Image-generating systems that can be used with the software include optical video cameras, digital X-ray cameras, phosphor storage plate scanner, extraoral X-ray devices, intraoral scanners and TWAIN compatible image sources. The software must only be used by authorized healthcare professionals in dental areas for the following tasks:

- Filter optimization of the display of 2D and 3D images for improved diagnosis
- Acquisition, storage, management, display, analysis, editing and supporting diagnosis of digital/digitised 2D and 3D images and videos
- Forwarding of images and additional data to external software (third-party software)

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

VistaSoft 4.0 and VisionX 4.0 imaging software is an image management system that allows dentists to acquire, display, edit, view, store, print, and distribute medical images. VisionX 4.0 / VistaSoft 4.0 runs on user provided PC compatible computers and utilize previously cleared digital image capture devices for image acquisition.

The software must only be used by authorized healthcare professionals in dental areas for the following tasks:

- Filter optimization of the display of 2D and 3D images for improved diagnosis
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The software is not intended for mammography use.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indication for use is the same. The VisionX 4.0 / VistaSoft 4.0 represents the enhancement to the current VisionX 3.0. Based on the flowchart Software of the Guidance document "Deciding when to submit a 510(K) for a software change to an existing device", the new features of the Software require a New 510(K).

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

New features from VisionX 4.0/ VistaSoft 4.0 in comparison to the VisionX 3.0 are:

- Image filter operations and annotations
- Interface to VistaSoft Cloud Drive
- Cybersecurity enhancements

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

We relied upon compliance with FDA recognized consensus standards and FDA guidance documents in the development of this software only device. The software was developed and tested in accordance with these FDA Guidance Documents: Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff AND Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff. Software verification and validation were conducted.

Here is a list of consensus standards that were employed in the development process;

ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices

ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer-

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical Device Software - Software Life Cycle Processes

IEC 82304-1 Edition 1.0 2016-10 Health software - Part 1: General requirements for product safety

IEC 81001-5-1 Edition 1.0 2021-12 Health Software and health IT systems safety effectiveness and security

IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices