January 15, 2026

Dgnct, LLC
℅ Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market St., Floor 23
PHILADELPHIA, PA 19103

Re: K252934
Trade/Device Name: Diagnocat
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical image analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: December 16, 2025
Received: December 16, 2025

Dear Kelliann Payne:

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

Lu Jiang Ph.D.
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DHT8B: Division of Radiologic Imaging
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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)*
K252934

Device Name
Diagnocat

Indications for Use *(Describe)*
Diagnocat software is a radiological, automated, concurrent read computer-assisted detection software intended to aid in the detection of periapical radiolucency on permanent teeth captured on maxillofacial Cone Beam CT images, using scans that were previously acquired for clinically justified purposes independent of Diagnocat. Diagnocat may be used only when a dental professional has independently determined that CBCT imaging is necessary for further evaluation of the patient. The device provides additional aid for the dental professional to use in their identification of periapical radiolucency. The device is not intended as a replacement for a complete dental professional's review or their clinical judgment that considers other relevant information from the patient or other images or patient history. The system is to be used by professionally trained and licensed dental professionals with the appropriate knowledge and training to interpret maxillofacial CBCT images, including at least two years of clinical experience reading and assessing CBCT scans.
Diagnocat is indicated for use by dental professionals for the second-read of CBCT radiographs of permanent teeth in patients 22 years of age or older.

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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K252934

510(k) Summary
DGNCT LLC's Diagnocat

Submitter

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Date Prepared: December 16, 2025

Name of Device: Diagnocat

Classification Name: Medical Image Analyzer

Regulatory Class: 21 CFR 892.2070

Product Code: MYN

Predicate Device: Overjet Periapical Radiolucency Assist (K231678)

Device Description

Diagnocat Software is a computer-assisted detection (CADe) software-only device intended to concurrently aid in the detection of periapical radiolucency areas. The device is designed to facilitate the analysis and interpretation of previously obtained dental Cone Beam Computed Tomography (CBCT) scans, specifically in cases where a periapical radiolucency condition is suspected, leveraging deep learning algorithms and artificial intelligence (AI). The key features of the software are:

1. Tooth Detection and Localization: Diagnocat employs image processing techniques to identify, number, and segment each tooth within a CBCT scan. The segmentation algorithm is employed to achieve tooth segmentation for tooth numeration and identification.

2. Periapical Radiolucency and Localization: The software uses computer vision models to distinguish between normal anatomical structures and areas suspected of periapical radiolucency, which is a radiographic sign of inflammatory bone lesions at the tooth's apex. The segmentation algorithm is used for both segmentation and heat mapping of regions suspected of periapical radiolucencies.

3. Image Visualization: Users can upload and navigate previously acquired CBCT studies. A panoramic reconstruction view aids users in navigating between a patient's teeth and identifying points of interest, and multiplanar reformatted (MPR) slices allow for detailed examination of each tooth.

The software also features non-device functions that supplement its achievement of the intended clinical use, including a user-friendly interface, the ability to integrate with various CBCT scanning devices, and cloud-based storage to facilitate access from multiple computers.

Intended Use / Indications for Use

Diagnocat software is a radiological, automated, concurrent read computer-assisted detection software intended to aid in the detection of periapical radiolucency on permanent teeth captured on maxillofacial Cone Beam CT images, using scans that were previously acquired for clinically justified purposes independent of Diagnocat. Diagnocat may be used only when a dental professional has independently determined that CBCT imaging is necessary for further evaluation of the patient. The device provides additional aid for the dental professional to use in their identification of periapical radiolucency. The device is not intended as a replacement for a complete dental professional's review or their clinical judgment that considers other relevant information from the patient or other images or patient history. The system is to be used by professionally trained and licensed dental professionals with the appropriate knowledge and training to interpret maxillofacial CBCT images, including at least two years of clinical experience reading and assessing CBCT scans.

Diagnocat is indicated for use by dental professionals for the second-read of CBCT radiographs of permanent teeth in patients 22 years of age or older.

The subject and predicate devices have the same intended use – to aid in the detection of periapical radiolucency. The minor differences in the specific indications for use (i.e., the input image type and target age range) do not alter the fundamental diagnostic purpose of the device or raise different questions of safety and effectiveness.

Summary of Technological Characteristics

The subject and predicate devices are both software-only, AI-based CADe devices that automate detection of suspected periapical radiolucency from pre-existing DICOM inputs. Thus, they have fundamentally the same principles of operation. Both devices analyze the input images by applying artificial neural network models to provide anatomical and tooth localizations and to detect periapical radiolucency, and thus have similar technological characteristics that do not raise any new safety and/or effectiveness questions.

The primary difference in technological characteristics is the type of image analyzed (predicate: 2D X-rays; subject device: CBCTs). However, both are medical images that are frequently relied upon for dental evaluations, and the underlying questions of safety and effectiveness are the same – centering around the device's ability to accurately localize the teeth present and identify periapical radiolucency. The output (i.e., detection of periapical radiolucency) and the intended use of the output (i.e., concurrent aid in HCP's diagnosis) are substantially equivalent, and performance testing validates each system's ability to analyze the respective image types in furtherance of the shared intended use. Similarly, the additional visual aids (e.g., tooth chart, annotated tooth card, panoramic reconstruction) generated by Diagnocat do not alter the intended use of the CADe algorithm or the detection results. The differences in compatible image formats and in the use of a web and/or desktop application are variations in implementation that also do not raise new questions of safety or effectiveness. A table comparing the key features of the two devices is provided below.

Table 1: Comparison of Diagnocat and Predicate Device

Criteria	Diagnocat (Subject Device)	Overjet Periapical Radiolucency Assist (Predicate Device) (K231678)
Classification	21 CFR 892.2070 (Medical Image Analyzer)	21 CFR 892.2070 (Medical Image Analyzer)
Product Code	MYN	MYN
Indications for Use	Diagnocat software is a radiological, automated, concurrent read computer-assisted detection software intended to aid in the detection of periapical radiolucency on permanent teeth captured on maxillofacial Cone Beam CT images, using scans that were previously acquired for clinically justified purposes independent of Diagnocat. Diagnocat may be used only when a dental professional has independently determined that CBCT imaging is necessary for further evaluation of the patient. The device provides additional aid for the dental professional to use in their identification of periapical radiolucency. The device is not intended as a replacement for a complete dental professional's review or their clinical judgment that considers other relevant information from the patient or other images or patient history. The system is to be used by professionally trained and licensed dental professionals with the appropriate knowledge and training to interpret maxillofacial CBCT images, including at least two years of clinical experience reading and assessing CBCT scans. Diagnocat is indicated for use by dental professionals for the second-read of CBCT radiographs of permanent teeth in patients 22 years of age or older.	Overjet Periapical Radiolucency (PARL) Assist is a radiological, automated, concurrent read computer-assisted detection software intended to aid in the detection of periapical radiolucency on permanent teeth captured on periapical radiographs. The device provides additional aid for the dentist to use in their identification of periapical radiolucency. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that considers other relevant information from the image or patient history. The system is to be used by professionally trained and licensed dentists. The Overjet Periapical Radiolucency Assist software is indicated for use on patients 12 years of age or older.
Inputs	CBCT images	2D X-rays
Automated Detection Outputs	1) Panoramic Reconstruction: CBCT visualization 2) Pathology Detection with Localization: CADe of suspected periapical radiolucency per tooth.	(1) Pathology Detection with Localization: CADe of suspected dental findings per tooth.
Dental Findings	Periapical radiolucency	Periapical radiolucency

Criteria	Diagnocat (Subject Device)	Overjet Periapical Radiolucency Assist (Predicate Device) (K231678)
Reader Workflow	Concurrent Reading	Concurrent Reading
Algorithm	Supervised machine learning	Supervised machine learning
Image Format	DICOM , JPEG, TIFF, PNG	JPG, PNG, EOP, JIF, DICOM
Configuration	Web and Desktop application	Desktop application

Performance Data

Nonclinical Testing

Software verification and validation testing, and cybersecurity testing per FDA guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", were conducted to ensure that the software meets its specifications and performs as intended.

Clinical Testing

Two separate standalone performance assessments compared the device's outputs against a reference standard established by expert radiologists. A Multi-Reader Multi-Case (MRMC) study was also performed, to evaluate improvements in diagnostic ability when using the device.

Study 1 - Segmentation (Teeth and Periapical Radiolucency)

Diagnocat's performance in the segmentation of teeth and periapical radiolucency (PARL) was evaluated using 100 CBCT images. The study was designed with two separate subject cohorts:

- Cohort 1: General population without confirmed PARL
- Cohort 2: Subjects with confirmed PARL in at least one tooth

As shown in the results table below, Diagnocat demonstrated strong agreement in segmentation of teeth and PARL with the reference standard. All Dice Similarity Coefficients (DSC) exceeded the pre-defined performance goals (PG).

Endpoint	Cohort	Mean DSC
Teeth Segmentation	Cohort 1	0.955
Teeth Segmentation	Cohort 2	0.947
Periapical Radiolucency Segmentation	Cohort 2	0.804

Results on the secondary metrics confirmed high performance, including consistent accuracy.

Study 2 - Detection of Periapical Radiolucency

Diagnocat's performance in the detection of periapical radiolucency (PARL) was evaluated using 285 CBCT images. As shown in the results table below, Diagnocat demonstrated strong agreement in

segmentation of PARL with the reference standard. Sensitivity (0.85) and specificity (0.99) both met the pre-defined PGs.

Metric	Mean
Sensitivity	0.854
Specificity	0.991

Secondary analysis by CBCT scanner manufacturer confirmed consistent performance in PARL detection across scanners.

Study 3 - MRMC

This study assessed whether the Diagnocat software improves radiologist performance in detecting PARL. As shown in the table below, the use of Diagnocat significantly improved clinician performance in detecting PARL. When aided by Diagnocat, the average area under the ROC curve (AUC) increased by 0.027 compared to unaided interpretation.

Reading Modality	AUC
Unaided	0.8940
Aided	0.9213
AUC Difference	+0.027

Secondary analysis of performance across important subgroups such as scanner manufacturer confirmed consistent performance/performance generalizability.

Conclusion:

Diagnocat is substantially equivalent to the Overjet Periapical Radiolucency Assist (K231678). Diagnocat has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications for use do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the Diagnocat and its predicate devices raise no new questions of safety or effectiveness. Performance data demonstrate that Diagnocat functions as intended and is as safe and effective as the Overjet Periapical Radiolucency Assist.