November 7, 2025

Bench7 Inc.
℅ Adam Heroux
Regulatory Consultant
Highland Biomedical Inc.
4190 Grove St
DENVER, CO 80211

Re: K250264
Trade/Device Name: SugarBug (1.x)
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: January 24, 2025
Received: October 7, 2025

Dear Adam Heroux:

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

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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)*
K250264

Device Name
SugarBug (1.x)

Indications for Use *(Describe)*
SugarBug is a radiological, automated, concurrent read, computer-assisted detection software intended to aid in the detection and segmentation of caries on bitewing radiographs. The device provides additional information for the dentist to use in their diagnosis of a tooth surface suspected of being carious. Sugarbug is intended to be used on patients 18 years and older. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that takes into account other relevant information from the image, patient history, and actual in vivo clinical assessment.

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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Contact Details 21 CFR 807.92(a)(1)

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Device Name 21 CFR 807.92(a)(2)

Device Trade Name: SugarBug (1.x)
Common Name: Medical image analyzer
Classification Name: Medical Image Analyzer
Regulation Number: 21 CFR 892.2070
Product Code(s): MYN

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate # K222746
Predicate Trade Name: Overjet Caries Assist
Product Code: MYN

Device Description Summary 21 CFR 807.92(a)(4)

SugarBug is a software as a medical device (SaMD) that uses machine learning to label features that the reader should examine for evidence of decay. SugarBug uses convolutional neural network to perform a semantic segmentation task. The algorithm goes through every pixel in an image and assigns a probability value to it for the possibility that it contains decay. A threshold is used to determine which pixels are labeled in the device's output. The software reads the selected image using local processing; images are not imported or sent to a cloud server any time during routine use.

Intended Use/Indications for Use **21 CFR 807.92(a)(5)**

SugarBug is a radiological, automated, concurrent read, computer-assisted detection software intended to aid in the detection and segmentation of caries on bitewing radiographs. The device provides additional information for the dentist to use in their diagnosis of a tooth surface suspected of being carious. Sugarbug is intended to be used on patients 18 years and older. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that takes into account other relevant information from the image, patient history, and actual in vivo clinical assessment.

Indications for Use Comparison **21 CFR 807.92(a)(5)**

The indications for use for the subject device are substantially similar to those for the predicate device. The primary differences include different patient ages and radiograph types. While minor differences exist between the proposed and predicate device, these changes do not raise new questions of safety or effectiveness, and do not change the device's fundamental intended use.

Technological Comparison **21 CFR 807.92(a)(6)**

The following information provides a summary of how the technological characteristics of the devices compare. The Sugarbug software is similar to the predicate with the following characteristics:

- Same intended use environment and user
- Similar output of caries detection via segmentation

The SugarBug software has the following differences from the predicate device:

- Different processing location - Sugarbug processes images locally without requiring cloud connection
- Different radiograph type - Sugarbug is for use with digital files of bitewing radiographs, while the predicate processes both bitewing and periapical radiographs
- Different processing input - Sugarbug processes screen captures as opposed to image file input
- Different dental X-ray sensors included in the product development and validation
- Different minimum image resolution - Sugarbug can process images of 300 pixel resolution while the predicate requires a minimum resolution of 500 pixels

SugarBug has undergone software and performance testing to ensure that any differences in the technological characteristics do not raise different questions of safety and effectiveness

Non-Clinical and/or Clinical Tests Summary & Conclusions **21 CFR 807.92(b)**

Summary of Non-clinical Testing:

Non-clinical testing consisted of Software Verification and Validation testing at the unit, integration, and system level to demonstrate that software requirements were implemented.

Standalone testing was conducted on a dataset of 400 de-identified images collected and labeled in the same procedure as the MRMC study discussed in the Clinical Testing Summary. Of the 400 images, 192 images contained caries (481 total lesions) while 208 were caries free.

SugarBug's lesion-level sensitivity and mean FPPI were 0.686 (0.655, 0.717) and 0.231 (0.111, 0.303), respectively. The DICE coefficient versus ground truth was 0.746 (0.724, 0.768).

Summary of Clinical Testing:

Clinical Study Design and Objectives:
A retrospective, multi-reader, multi-case (MRMC) study was conducted to compare the diagnostic performance of dental practitioners (readers) when aided by the SugarBug software to their performance when unaided. 12 US licensed dentists served as readers, each evaluating the same set of 300 bitewing radiographs under two conditions: (1) unaided and (2) aided by SugarBug. Readers were asked to identify areas of suspected decay by filling in the area with an annotation tool. A washout period of 30 days was applied between the two reading sessions to minimize recall bias. Images were presented to each reader in a randomized order. The reading sequence (aided first versus unaided first) was also randomized. Each reader was asked to provide a confidence score for each lesion they labeled. The primary objective was to determine whether SugarBug improves diagnostic performance, as measured by weighted Alternative Free-response Receiver Operating Characteristic (wAFROC) area under the curve (AUC). Secondary objectives included evaluating reader changes in sensitivity, specificity, and annotation quality (DICE scores), as well as assessing standalone model performance of SugarBug.

Clinical Study Population and Data Collection:
300 de-identified bitewing radiographic images of patients aged 18 and older from the US were included. No procedures were performed solely for this study. All images were retrospectively collected from routine dental examinations. The images were sampled to be representative of a range of x-ray sensor types. Within the set, the relative representation of sensor type was: Vatech HD 29%, iSensor H2 11%, Schick 33: 45%, Dexis Platinum 15%. The patients' ages ranged from 18 to 87 with a mean age of 42. Approximately 47% of the patients were male and 53% were female. 133 images in the dataset contained caries while 167 were caries free. Annotations were carried out by 12 US licensed dentists. Ground truth was established by the

consensus labels of 3 US licensed general dentists with an average of 27 years of clinical experience.

Clinical Study Results:

- Primary Endpoint (wAFROC-AUC): The mean unaided reader wAFROC-AUC was 0.659 (0.611,0.707) while the mean aided reader wAFROC-AUC was 0.725 (0.683, 0.767). This shows an improvement of 0.066 (0.030, 0.102) with a p-value of 0.001.This demonstrates a statistically significant improvement in diagnostic accuracy when readers were aided by SugarBug.

- Lesion-Level Sensitivity and FPPI: Aided readers' lesion-level mean sensitivity was 0.674 (0.615, 0.728) while that of unaided readers was 0.540 (0.445, 0.621).This demonstrates a statistically significant improvement of 0.134 (0.066, 0.206).

  Aided readers showed a mean FPPI of 0.325 (0.128, 0.310) while unaided readers had a mean FPPI of 0.328 (0.102, 0.331). This demonstrates a very small improvement of -0.003 (-0.103, 0.086), although this difference was not statistically significant.

- DICE Scores (Readers): Mean DICE scores (lesion annotation similarity relative to ground truth) were 0.695 (0.688, 0.702) for unaided readings and 0.740 (0.733, 0.747) for aided readings, resulting in a mean difference of 0.045 (0.035,0.055). Although this difference is modest, it suggests an improvement in lesion delineation.

Clinical Study Conclusions:
The study results indicate that SugarBug-aided readers exhibit statistically significant improvements in overall diagnostic performance (wAFROC-AUC) for the detection of dental caries compared to unaided readers.

Overall Conclusions:

The Non-Clinical and Clinical testing have demonstrated that SugarBug shows substantially equivalent performance to the predicate device.