Imaging Biometrics, LLC
Timothy Dondlinger
COO
13416 Watertown Plank Road, Suite 260
ELM GROVE, WISCONSIN 53122

September 26, 2019

Re: K191530
Trade/Device Name: StoneChecker
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 7, 2019
Received: June 10, 2019

Dear Timothy Dondlinger:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
191530

Device Name
StoneChecker

Indications for Use *(Describe)*
StoneChecker is a standalone post-processing software application which assists trained professionals in evaluating DICOM computed tomography image studies of patients diagnosed with kidney stones. The software provides tools to enable the user to navigate images, select regions of interest, and generate information from those regions.

The generated information consists of regional statistical measurements of image texture and heterogeneity, including means, standard deviation, skewness, and kurtosis. The information also includes regional physical measurements of stone size, volume, and position.

StoneChecker does not make clinical decisions and the information provided by StoneChecker must not be used in isolation when making patient management decisions.

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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510(k) Summary

510(k) Notification K191530

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant / Owner :	Imaging Biometrics, LLC 13416 Watertown Plank Road, Suite 260 Elm Grove, WI 53122
Contact Person:	Timothy Dondlinger (262) 439-8252 (telephone) (262) 439-8301 (fax) tim@imagingbiometrics.com
Date Prepared:	June 7, 2019
Common Name:	System, Image Processing, Radiological
Trade Name:	StoneChecker
Classification Name:	Picture archiving and communications system
Review Panel:	Radiology
Regulation Number:	892.2050
Device Class:	II
Product Code:	LLZ

Predicate Device Information

510(k)	Trade Name	Manufacture	Type	Regulation Number
K141745	IQQA-BodyImaging Software	EDDA Technology	Primary Predicate	892.2050
K110332	ClearCanvas RIS/PACS	ClearCanvas, Inc.	Secondary Predicate	892.2050

Device Description

StoneChecker (SC) is a standalone software application intended to load DICOM-formatted CT studies, let the trained user identify stone regions of interest, and provide computed information consisting of physical measurements and statistical measurements of stone heterogeneity from a single source making it easier for the user to determine the best treatment option. SC is an optional tool used during the treatment planning of a patient diagnosed with kidney stones.

StoneChecker provides the user tools to select and evaluate various physical characteristics of a kidney stone displayed on a non-contrast enhanced Kidneys, Ureters, and Bladder (KUB) CT scan slice. The measurement and calculated values are displayed on the PC screen for the user and the user has an option to generate a report. The calculated output includes stone volume, mean Hounsfield Unit (HU) density, skin to stone distance, and texture values (mean, mean of positive pixels, standard deviation, skewness, kurtosis, and entropy). This data can be used by the physician as an aid to decision making and are intended to be an adjunct to other clinical data such as medical history, physical examination, and urine analysis. Thus, additional analysis of all kidney stones is required. StoneChecker software is designed exclusively for use in assessing kidney stones.

StoneChecker is designed to provide easy-to-acquire useful data for helping clinicians make the best decisions for their patients.

StoneChecker includes the following features:

- Processes standard DICOM image sets,
- Novel proven statistical algorithms,
- Time-saving kidney stone regions of interest (ROI) and measurement tools,
- Rapid calculation results, and
- Saves results in standard Excel spreadsheets.

Indications for Use

StoneChecker is a standalone post-processing software application which assists trained professionals in evaluating DICOM computed tomography image studies of patients diagnosed with kidney stones. The software provides tools to enable the user to navigate images, select regions of interest, and generate information from those regions.

The generated information consists of regional statistical measurements of image texture and heterogeneity, including means, standard deviation, skewness, and kurtosis. The information also includes regional physical measurements of stone size, volume, and position.

StoneChecker does not make clinical decisions and the information provided by StoneChecker must not be used in isolation when making patient management decisions.

Substantial Equivalence

Intended Use	Subject	Primary IQQA Body Imaging Software (K141745)	Secondary ClearCanvas RIS / PACS (K110332)
1. To be used on standard PC based hardware.	Yes	Yes	Yes
2. To be run as medical device standalone software.	Yes	Yes	Yes
3. To be used to load standard DICOM CT studies.	Yes	Yes	Yes
4. To be used by clinicians to identify region of interests (ROIs).	Yes	Yes	Yes
5. To be used for displaying, measuring, and analyzing images controlled by the user.	Yes	Yes	Yes
6. To be used for providing output used in the treatment of a patient.	Yes	Yes	Yes

Subject Device (Indications for Use): StoneChecker
StoneChecker is a standalone post-processing software application which assists trained professionals in evaluating *DICOM* computed tomography image studies of patients diagnosed with kidney stones. The software provides tools to enable the user to navigate images, select regions of interest, and generate information from those regions. The generated information consists of regional statistical measurements of image texture and heterogeneity, including means, standard deviation, skewness, and kurtosis. The information also includes regional physical measurements of stone size, volume, and position. StoneChecker does not make clinical decisions and the information provided by StoneChecker must not be used in isolation when making patient management decisions.
Primary Predicate IFU Statement: IQQA-BodyImaging Software (K141745)
IQQA-BodyImaging is a PC-based, self-contained, non-invasive image analysis software application for reviewing body imaging studies (including thoracic, abdominal and pelvic) derived from CT and MR scanners. Combining image viewing, processing and reporting tools, the software is designed to support the visualization, evaluation, and reporting of body imaging studies and physician-identified lesions. The software supports a workflow based on automated image registration for viewing and analyzing multiphase and multiple time-point volume datasets. It includes tools for interactive segmentation and labeling of organ segments and vascular/ductal/airway structures. The software provides functionalities for manual or interactive segmentation of physician-identified lesions, interactive definition of virtual resection plane and virtual needle path and allows for regional volumetric analysis of such lesions in terms of size, position, margin, and enhancement pattern, providing information for physician's evaluation and treatment planning, monitoring, and follow-up. The software is designed for use by trained professionals, including physicians and technicians. Image source: DICOM.
Secondary Predicate IFU Statement: ClearCanvas RIS/PACS (K110332)
The ClearCanvas RIS/PACS is an image management system whose intended use is to provide scaleable DICOM compatible PACS solutions for hospitals and related institutions and sites, which will archive, distribute, retrieve and display images and data from all hospital modalities (such as CR, CT, DR, MR, and other devices) and information systems. This also includes the display of structured reports and mammography images that have been created according to DICOM "For Presentation", and will include standard features and other tools for analyzing mammography images. Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammography images may only be interpreted using an FDA approved monitor that offers at least 5 mega-pixel resolution and meets other technical specifications approved by the FDA.

Use Characteristic	Subject	IQQA Body Imaging Software (K141745)	ClearCanvas RIS / PACS (K110332)
Indications for Use Statements			
1. Statement references a software only device.	Yes	Yes	Yes
2. Statement references DICOM standard.	Yes	Yes	Yes
3. Statement references the display / view of medical images.	Yes	Yes	Yes
4. Statement references the output of information.	Yes	Yes	Yes
5. Statement references the user selection of ROIs	Yes	Yes	No
6. Statement references providing the clinician with information about an ROI.	Yes	Yes	No
7. Statement references providing the user with information related to kidney stones.	Yes	No	No
8. Intended Users	Trained physicians, Radiologists.	Trained professional, including physicians and technicians	Physicians, Radiologists, clinicians, or technologists.
9. Target population	Patients diagnosed with kidney stones that require medical intervention.	No restrictions	No restrictions
10. Anatomical sites	Kidneys, ureters, and bladder (KUB)	Body imaging studies (including thoracic, abdominal and pelvic)	No restrictions
11. Where used	No restrictions	No restrictions	No restrictions

A comparison of the devices' technical characteristics is summarized in the following table:

Technical Characteristic[1]	Subject	IQQA Body Imaging Software (K141745)	ClearCanvas RIS / PACS (K110332)
Design			
1. Standalone software device that operates on off-the-shelf hardware.	Yes	Yes	Yes
2. Software device uses standard windowing user interface.	Yes	Yes	Yes
3. Software device uses software algorithms for image post processing analysis.	Yes	Yes	Yes
4. Conforms to DICOM standards (PS 3.10)	Yes	Yes	Yes
Features and Capabilities			
5. Data loading of CT image series using DICOM standard	Yes	Yes	Yes
6. 2D image review	Yes	Yes	Yes
7. Image navigation tools (pan, zoom, scroll, window/level)	Yes	Yes	Yes
8. Measurement tools (ruler, ROI)	Yes	Yes	Yes
9. Size calculations (area, volume)	Yes	Yes	Area
10. Statistical calculations	Mean, standard deviation (SD), mean of positive pixels, skewness, kurtosis, entropy	Regional volumetric analysis of physician-identified lesions in terms of size, position, margin, and enhancement pattern	Mean, SD
11. CT texture analysis calculations[2]	Yes	Yes	No
12. Display output of measurements and information.	Yes	Yes	Yes
13. Report generation	Excel	Unknown	DICOM Print
Physical Characteristics			
14. Post-processing (non-real-time, non-contacting, non-life supporting and not life sustaining).	Yes	Yes	Yes

[1] Because the subject and predicate devices have no patient contact and do not control any life sustaining devices, several areas of comparison were considered not relevant and are not discussed in this table.

[2] The CT texture analysis calculations of the subject device consist of the statistical calculations listed (mean, standard deviation, mean of positive pixels, skewness, kurtosis, and entropy) computed from image intensity data which has first been processed through a Laplacian of Gaussian filter, effectively highlighting features of different sizes.

The intended use and technical characteristics for StoneChecker are similar to both predicate devices listed in the Predicate Device Information section above for a stand-alone software application that provides a user interface to allow a clinician to load, display, measure, and identify regions of interests. The software algorithms calculate statistical information based on the intensities of the image pixels contained within the regions of interest. The calculated values provide a clinician with relevant information for stone evaluation.

SC is operated as stand-alone software, is non-patient contacting, and is used by trained physicians. SC does not provide any interpretation of the statistical parameters displayed to the user. The trained physician is responsible for identifying, measuring, and interpreting the images and data being displayed.

SC and both its predicate devices are substantially equivalent in the categories of technical characteristics and features. SC does not raise any different questions of safety or effectiveness as demonstrated through performance testing and is therefore substantially equivalent to the predicate device.

Standards Conformance

During the development of StoneChecker, the following standards were observed:

Standard	FDA Recognition Number
NEMA PS 3.1 – 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM)	12-300
ISO 14971 Second edition 2007-03-01 Medical devices – Application of risk management to medical devices	5-40
ANSI AAMI IEC 62304:2006 Medical device software – Software life cycle processes	13-32

Testing Information and Performance

All product specifications were verified and validated. Testing was performed according to internal company procedures. Software testing and validation were conducted according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent. Testing was performed in accordance with the FDA guidance document, "*General Principles of Software Validation*," issued January 11, 2002.

Bench testing (functional and integration) was conducted for StoneChecker during product development. Test results demonstrate StoneChecker output is computed accurately based on input. However, to obtain consistent output, stones to be analyzed should be at least 5mm in size, and images should be obtained at resolutions with sub-mm pixel sizes. StoneChecker texture analysis calculations are extremely sensitive to changes in resolution, so image resolutions must be constant, and, ideally, slice thicknesses and spacing should also be similar.

To supplement the software verification, StoneChecker underwent usage validation at two clinical sites in Oxford, UK and Beijing, China. The purpose of the testing was to have physicians use StoneChecker to analyze KUB CT scans, validate major functionalities provided by StoneChecker, and provide feedback on the clinical usability of StoneChecker. Where appropriate, tester feedback was incorporated into StoneChecker software modifications.

The StoneChecker risk analysis was completed and risk control measures were implemented to mitigate unacceptable hazards. StoneChecker relies upon user

expertise to determine the usability of images for analysis. Images with excessive noise, distortion, and/or artifacts obscuring any portion of a stone should not be used for analysis. Testing for verification and validation of StoneChecker was found acceptable to support the claims of substantial equivalence.

Conclusion

StoneChecker has the same intended use as the predicate devices. The technological characteristics such as software platform, CT series loading, image viewing, and measurement tools are the same. Any differences between StoneChecker and the predicate devices do not raise different questions of safety and effectiveness. The result of all testing conducted was found acceptable to support the claim of substantial equivalence.