Nines, Inc.
% John J. Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
555 13th Street, NW
WASHINGTON DC 20004

February 25, 2021

Re: K202990
Trade/Device Name: NinesMeasure
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 22, 2021
Received: January 22, 2021

Dear Dr. Smith:

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 and Part 809); 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 T. 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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K202990

Device Name

NinesMeasure

Indications for Use *(Describe)*

NinesMeasure is a semi-automatic tool indicated for use by trained radiologists to aid in the analysis and review of adult thoracic CT images. NinesMeasure provides quantitative information about pulmonary nodule size on a single study or over the time course of several thoracic studies by providing long and short axis diameter measurements in the axial plane.

Based on analysis of DICOM images and provided input from a radiologist, indicating the location of the pulmonary nodule, the device uses artificial intelligence algorithms to automatically perform the measurements, and allows the axial measurements to be displayed and reviewed. NinesMeasure is limited for use on solid pulmonary nodules.

The device is intended to be used as a measurement tool by a trained radiologist and is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm a diagnosis. The device does not alter the original medical image.

Type of Use *(Select one or both, as applicable)*

X 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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510(k) SUMMARY
Nines, Inc.'s NinesMeasure
K202990

Submitter:

Nines, Inc
329 Alma Street
Palo Alto, CA 94301

Contact Person:

Dr. Russell Stewart
Phone: 650 924 6159
russell@nines.com

Date Prepared: January 22, 2021

Name of Device: NinesMeasure

Classification Name: System, Image processing, Radiological

Regulatory Class: Class II

Product Code: LLZ

Predicate Device: Philips Medical Systems Nederland B.V.'s Lung Nodule Assessment and Comparison Option (LNA) (K162484)

Device Description

NinesMeasure is a semi-automatic, diagnostic patient imaging tool used to measure the size of selected pulmonary nodules in a radiological image. The software system is comprised of a set of software modules for performing image analysis at a specified image location to calculate measurements of pulmonary nodules on adult thoracic CT images. The system operates over a standard network interface and receives the DICOM images and coordinates of the pulmonary nodule to measure. The system then returns the measurements for the long and short axis diameters for review by a trained radiologist.

NinesMeasure is designed to be used with a standard PACS, where the user can indicate a location of the pulmonary nodule to measure, and then review and edit the measurements on the DICOM image.

The image analysis uses Artificial Intelligence (AI) technology to analyze chest CT images for computing the measurements. Specifically, the device utilizes a machine learning (ML) algorithm to compute segmentations of nodules, from which the long and short axis measurements are then calculated.

Intended Use / Indications for Use

NinesMeasure is a semi-automatic tool indicated for use by trained radiologists to aid in the analysis and review of adult thoracic CT images. NinesMeasure provides quantitative information about pulmonary nodule size on a single study or over the time course of several thoracic studies by providing long and short axis diameter measurements in the axial plane.

Based on analysis of DICOM images and provided input from a radiologist, indicating the location of the pulmonary nodule, the device uses artificial intelligence algorithms to automatically perform the measurements, and allows the axial measurements to be displayed and reviewed. NinesMeasure is limited for use on solid pulmonary nodules.

The device is intended to be used as a measurement tool by a trained radiologist and is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm a diagnosis. The device does not alter the original medical image.

Summary of Technological Characteristics

The NinesMeasure has similar technological characteristics as the predicate. Both devices utilize image processing algorithms that calculate pulmonary nodule measurements and return the measurements to the workstation. Although the predicate is cleared for multiple features in addition to pulmonary nodule measurements, these minor differences do not impact the safety of the subject device.

A table comparing the key features of the subject and predicate device is provided below.

	NinesMeasure K202990	**Philips Medical Systems' Lung Nodule Assessment and Comparison Option (LNA)(K162484)**
Device Classification Name	System, Image processing, Radiological	System, Image processing, Radiological
Device Class	Class II	Class II
Classification Panel	Radiology	Radiology
Product Code	LLZ	LLZ, JAK
Regulation Description	Radiological Image Processing Software	Radiological Image Processing Software
Regulation Number	21 CFR 892.2050	21 CFR 892.2050 21 CFR 892.1750
Indications for Use	NinesMeasure is a semi-automatic tool indicated for use by trained radiologists to aid in the analysis and review of adult thoracic CT images. NinesMeasure provides quantitative information about pulmonary nodule size on a	The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about

	single study or over the time course of several thoracic studies by providing long and short axis diameter measurements in the axial plane. Based on analysis of DICOM images and provided input from a radiologist, indicating the location of the pulmonary nodule, the device uses artificial intelligence algorithms to automatically perform the measurements, and allows the axial measurements to be displayed and reviewed. NinesMeasure is limited for use on solid pulmonary nodules. The device is intended to be used as a measurement tool by a trained radiologist and is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm a diagnosis. The device does not alter the original medical image.	nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.
User Population	Radiologists	Radiologists and Technologist
Technological Characteristics	Image processing algorithms computing pulmonary nodule measurements and returning computed measurements to the workstation.	Image processing algorithms computing pulmonary nodule measurements and returning computed measurements to the workstation.
Components	Image processing algorithms for nodule measurement	-Image processing algorithms -Display, comparison, and risk calculations
Anatomical region of interest	Chest	Chest
Features	-long axis measurement -short axis measurement (perpendicular to long axis)	-long axis measurement -short axis measurement (perpendicular to long axis) -Average/Max 3D/Effective diameter (mm) -Volume (mm^3) -Mean Densities (HU) -Segmentation of lung airway, lungs and lung lobes -Single click lung nodule segmentation -Nodule Characteristics -Comparison and matching -Automatic calculation of

		doubling time, percent and absolute change of all numerical parameters -Reporting results functions including dictation table, patient related information, LungRads, and Risk Calculator -Printing option

Performance Testing

Nines performed software verification and validation testing that covers the performance of the algorithms, as well as the performance of the software and its components. In all instances, NinesMeasure functioned as intended and expected.

The algorithm performance was validated with a retrospective, multi-center image comparison study. The study was performed to evaluate the NinesMeasure device and demonstrate the product's performance as a workflow tool for pulmonary nodule measurement consistent with the proposed indications for use. The test dataset was diverse, and included 3 different major scanner manufacturers, 7 different scanner models, 11 different clinical sites.

The primary endpoints of the algorithm are listed below:

Primary Endpoint - All Nodules	**Result**
Normalized error on long axis diameter [95% CI]	0.113 [Upper Bound 0.124]
Normalized error on short axis diameter [95% CI]	0.131 [Upper Bound 0.143]

The primary endpoint stratified by nodule size is listed below:

Nodule size	**Number of nodules**	**Normalized error on long axis diameter [95% CI]**	**Normalized error on short axis diameter [95% CI]**
3-6 mm	100	0.104 [Upper Bound: 0.119]	0.123 [Upper Bound: 0.139]
6-8 mm	63	0.119 [Upper Bound: 0.138]	0.143 [Upper Bound: 0.161]
8-10 mm	46	0.13 [Upper Bound 0.156]	0.133 [Upper Bound 0.166]

The performance goals for the primary endpoints were met.

Based on the clinical performance as documented in the clinical study, the subject software has a safety and effectiveness profile that is similar to the predicate device.

Conclusions

NinesMeasure has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the technological differences between NinesMeasure and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that NinesMeasure performs as intended. Thus, NinesMeasure is substantially equivalent.