April 14, 2023

Nonagon Ltd.
℅ Jonathan Kahan
Partner
Hogan Lovells US LPP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K223785
Trade/Device Name: N9+
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, FLL, DQA, ERA,
Dated: March 23, 2023
Received: March 23, 2023

Dear Jonathan Kahan:

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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
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)*
K223785

Device Name

N9+ (OTC) device

Indications for Use *(Describe)*

The N9+ (OTC) device, combined with a smartphone application, is a multiple-sensor device that is intended to measure, record, and transmit the recorded data of auscultation sound of human body, human body temperature, oxygen saturation (SpO2) and pulse rate, and images of an examined body part.

N9+ (OTC) device is intended for use by adult lay users in a non-clinical environment. Nonagon application enables counseling with the physician and transmission of the information over an IP network.

The oxygen saturation (SpO2) sensor of the device is for Rx only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional Premarket Notification Submission – 510(k)
N9+ (OTC) device
510(k) Number K223785

Date Prepared: April 13, 2023

I. SUBMITTER

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II. DEVICE

Name of Device:	N9+ (OTC) device
Common or Usual Name:	Patient Monitor
Classification Name:	Oximeter, Clinical Electronic Thermometer, and Otoscope
Regulatory Class:	Class II
Product Code:	DQD, FLL, DQA, ERA

III. PREDICATE DEVICE

Primary predicate:

MyHomeDoc device (K202483),
Regulation Number: 870.1875
Classification Product Code: DQD
Subsequent Product Codes: DQA, ERA, FLL

Secondary predicates:

Tyto Care Ltd. Tyto Thermometer (OTC) cleared under K190242
Regulation Number: 21 CFR 880.2910
Product Code: FLL

TytoCare Ltd. Tyto Stethoscope (OTC) cleared under K181612
Regulation Number: 21 CFR 870.1875
Product Code: DQD

IV. DEVICE DESCRIPTION

The N9+ (OTC) (except for the oxygen saturation function), is a home use device. The device is comprised of a handheld unit that interfaces with a smartphone, a wireless otoscope kit comprised of the otoscope camera, a reusable tongue depressor and 2 reusable ear specula (adult and toddlers) and a dedicated smartphone software application that runs on the user's personal smartphone.

The system uses the smartphone's camera to record images of the patient's skin.

An API is defined to enable healthcare providers to communicate with the device. The pulse oximeter will be a prescription device in the US market.

The Device enables user's examination at home with or without the guidance of a remote physician. It also enables guidance and data examination by a remote physician over an IP network. The Smartphone Application controls the Handheld Unit and wireless otoscope functionality (besides recording images of the patient's skin) and processes and displays the collected data.

V. INDICATIONS FOR USE

The N9+ (OTC) device, combined with a smartphone application, is a multiple-sensor device that is intended to measure, record, and transmit the recorded data of auscultation sound of human body, human body temperature, oxygen saturation (SpO2) and pulse rate, and images of an examined body part.

N9+ (OTC) device is intended for use by adult lay users in a non-clinical environment. Nonagon application enables counseling with the physician and transmission of the information over an IP network.

The oxygen saturation (SpO2) sensor of the device is for Rx only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE AND REFERENCE DEVICE

The N9+ (OTC) have the same intended use as the previously cleared device, with a modification to the indications for use to allow for OTC use (except for the pulse oximeter which remains under prescription use). The N9+ (OTC) device has substantially similar technology as the cleared N9+ and the secondary predicate devices and the minor differences do not raise new or different questions of safety or effectiveness.

N9+ (OTC) device K223785	**MyHomeDoc device (N9+) K202483**	**Tyco Care Tyto Stethoscope (OTC) K181612**	**Tyto Care Tyto Thermometer (OTC) K190242**
The N9+ (OTC) device, combined with a smartphone application, is a multiple-sensor device that is intended to measure, record, and transmit the recorded data of auscultation sound of human body, human body	The MyHomeDoc device, combined with a smartphone application, is a multiple-sensor device that is intended to measure, record, and transmit the recorded data of auscultation sound of human body,	The Tyto Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location on an IP	The Tyto Thermometer is a non - contact clinical infrared thermometer intended for intermittent determination of human body temperature from the

N9+ (OTC) device K223785	MyHomeDoc device (N9+) K202483	Tyco Care Tyto Stethoscope (OTC) K181612	Tyto Care Tyto Thermometer (OTC) K190242
temperature, oxygen saturation (SpO2) and pulse rate, and images of an examined body part. N9+ (OTC) device is intended for use by adult lay users in a non-clinical environment. Nonagon application enables counseling with the physician and transmission of the information over an IP network. The oxygen saturation (SpO2) sensor of the device is for Rx only.	human body temperature, oxygen saturation (SpO2) and pulse rate, and images of an examined body part. MyHomeDoc device is intended for use by adult lay users in a non-clinical environment. MyHomeDoc application enables counseling with the physician and transmission of the information over an IP network.	network can listen to the auscultation sounds of a patient on site or at a different location on the IP network with the signal carried on an IP connection between the two locations. The Tyto Stethoscope is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is for medical diagnostics purposes only. The device is not intended for self-diagnosis.	center of the forehead on people of all ages. The Tyto Thermometer is intended for use by both adult lay users and clinicians. It can be used both at home and in clinic environments.

No significant changes to the technological characteristics of the device have been implemented since clearance except for a modification to the otoscope due to a change in supplier.

The N9+ (OTC) device has similar technological characteristics as the predicate device in that it is provides the same exams, used at home by the patient directly to record and wirelessly transmit the patient's data to the healthcare provider at a different location in either an online or offline mode. The secondary predicate devices provide similar functionalities as the N9+ (OTC) device and also allows for OTC use. With the subject and predicate devices, none of the systems provide any interpretation of the data.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- **Biocompatibility testing** in compliance with ISO 10993.

- **Software Validation**
  The N9+ (OTC) software level of concern is moderate. Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

- **Electrical Safely and EMC**
  Electrical Safety per IEC 60601-1 and Electromagnetic compatibility (EMC) per IEC 60601-1-2 were conducted on the N9+ (OTC) device. In addition, the system complies with IEC 60601-1-11, IEC 62471, and IEC 60601-2-18.

- **Wireless quality of service and coexistence testing**
  Testing was performed to address testing of the device in the presence of the relevant potential emitters in the intended use environment in accordance with ANSI C63.27-2017: Evaluation of wireless coexistence and FDA's Guidance "Radio frequency wireless technology in medical devices."

- **Self-Selection testing**
  The study enrolled 31 men and women of different ages and literacy levels. All the participants made a correct purchasing decision. The results of this self-selection study show that consumers are able to decide whether the N9+ (OTC) is right for them based on the information communicated on the outer package (box).

VIII. CONCLUSIONS

The N9+ (OTC) device was determined to be substantially equivalent to the predicate devices.