DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 31, 2017

DGH Technology, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K171301
Trade/Device Name: Scanmate Flex
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: July 25, 2017
Received: July 26, 2017

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171301

Device Name
Scanmate Flex

Indications for Use *(Describe)*
The Scanmate Flex is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power. The Scanmate Flex is intended for the examination of adult patients.

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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System: Scanmate Flex: Ultrasound System

Probe(s): DGH6006: A-Scan Probe

DGH1912: B-Scan Probe (12.5 MHz)

DGH1920: B-Scan Probe (20 MHz)

DGH1500: UBM Probe (35 MHz or 50 MHz)

Intended Use: The Scanmate Flex is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power. The Scanmate Flex is intended for the examination of adult patients.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (A-Mode)
Ophthalmic	Ophthalmic	N						N
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Probe: DGH6006: A-Scan Probe

Intended Use: The DGH6006 probe is used for measuring the Axial Length (AXL), Anterior Chamber Depth (ACD), Lens Thickness (LT), and the Vitreous Chamber Depth (VCD). The probe contacts the cornea directly.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (A-Mode)
Ophthalmic	Ophthalmic							P (K093371)
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

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Probe: DGH1912: B-Scan Probe (12.5 MHz)

Intended Use: The DGH1912 probe is used for imaging the posterior segment of the globe. The probe contacts the cornea directly.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (A-Mode)
Ophthalmic	Ophthalmic	N						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

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Probe: DGH1920: B-Scan Probe (20 MHz)

Intended Use: The DGH1920 probe is used for imaging the posterior segment of the globe. The probe contacts the cornea directly.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (A-Mode)
Ophthalmic	Ophthalmic	N						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

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Probe: DGH1500: UBM Probe

Intended Use: The DGH1500 is used for imaging the anterior segment of the globe. The probe may operate at a nominal frequency of 50 MHz or 35 MHz, depending on transducer selected.

The DGH1500 is an open probe and must be with the FDA-cleared ClearScan probe cover.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (A-Mode)
Ophthalmic	Ophthalmic	N						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-Operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

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DGH TECHNOLOGY, INC.

510(k) Summary

(21 CFR 807.92)

I. Submitter

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Date Prepared: July 17th, 2017

II. Device

Name of Device: Scanmate Flex
Common or Usual Name: Diagnostic ophthalmic ultrasound system
Classification Name: System, imaging, pulsed echo, ultrasonic
Regulatory Class: II
21 CFR 892.1560
Product Code: IYO, ITX

III. Predicate Devices

Predicate devices: Sonomed VuPad (K140199) and DGH 6000 Scanmate A (K093371).

Neither of these predicates has been subject to a design-related recall.

IV: Device Description

The Scanmate Flex is a diagnostic ultrasound system that allows eyecare professionals to visualize and measure internal structures of the eye. The technology is based on ultrasonic pulse echo technology, whereby short bursts of ultrasonic energy are transmitted and the resulting echoes are captured, amplified, filtered and processed. The timing of the echoes is analyzed and converted into distance information (when the A-Scan probe is used) or images (when the B-

Scan and UBM probes are used). The distance information and images are displayed on a PC screen.

The Scanmate Flex consists of an interface module (which is connected to a standard Windows PC, not included with the Scanmate Flex system) and one or more optional ultrasound probes. The Scanmate Flex supports the following probe types:

- DGH6006 A-Scan Probe (10 MHz)
- DGH1912 B-Scan Probe (12.5 MHz)
- DGH1920 B-Scan Probe (20 MHz)
- DGH1500 UBM Probe (35 MHz and 50 MHz)

V. Intended Use

Scanmate Flex Indications for Use

The Scanmate Flex is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power. The Scanmate Flex is intended for the examination of adult patients.

Comparison to Predicate Device Indications for Use

Predicate Manufacturer and Device Name	**Predicate 510(k)**	**Indications for Use**
Sonomed VuPad	K140199	The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.
DGH Technology, Inc. DGH 6000 Scanmate A	K093371	The intended use of the DGH 6000 is the measurement of AL, ACD, LT of the human eye. The DGH 6000 is also intended to calculate the optical power of an IOL that is to be implanted during cataract surgery.

The Scanmate Flex Indications for Use are identical to the Predicate Device (Sonomed VuPad K140199), except for the device name and the restriction that it be used with adult patients. There are no clinically significant differences between the Scanmate Flex and the DGH 6000 (K093371) Indications for Use related to A-Mode operation.

VI. Comparison of Technological Characteristics with the Predicate Devices

DGH Technology believes that the technological characteristics incorporated in the Scanmate Flex are substantially equivalent to those of the Sonomed VuPad and DGH 6000 Scanmate A. The DGH 6000 only supports A-Mode operation, so characteristics related to B-Mode functions are only compared to the Sonomed VuPad. Both the subject and predicate devices are based on the same ultrasound imaging and measurement principles. The major technological aspects they have in common are the following:

- Ophthalmic A-mode and B-mode scanning for imaging and measurement.
- Ultrasound frequencies ranging from 10 MHz to 50 MHz.
- Windows PC or tablet for operator controls and display of measurements and images.
- Database for storage of measurements and images.
- ClearScan disposable cover for UBM probe.
- Standard power calculations for intra-ocular lens selection.

The following primary technological differences exist between the subject and predicate devices:

- The subject device has a battery and can be operated without being plugged into A/C power; the predicate devices require mains power.
- The subject device and DGH 6000 Scanmate A predicate can be used with an existing Windows computer; the Sonomed VuPad predicate must be used with a dedicated tablet computer.

VII. Performance Data

The following tests were performed to demonstrate substantial equivalence.

Acoustic Output Testing

Acoustic output testing of the Scanmate Flex was performed by Acertara Acoustic Laboratories and Sonora Medical Systems.

Performance Testing

The measurement performance of the Scanmate Flex was verified using precision test blocks and monofilament phantoms.

Thermal, Mechanical, and Electrical Performance

The DGH Scanmate Flex conforms to the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod). (General II (ES/EMC)

- IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests. (General II (ES/EMC))

- IEC 60601-2-37 Edition 2.0 2007, Medical Electrical Equipment - Part 2-37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment. (Radiology)

- NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment - Revision 3. (Radiology)

- NEMA UD-3 2004 Standard for real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

- AAMI / ANSI / ISO 10993-1:2009/(R)2013, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process. (Biocompatibility)

Biocompatibility Testing

The Scanmate Flex has four patient-contacting elements: the A-Scan Probe, the B-Scan Probe, the ClearScan disposable cover of the UBM probe, and the immersion shell of the A-Scan Probe (if used). In all cases, the patient-contacting materials were found to be biocompatible.

Software Verification and Validation Testing

The software of the Scanmate Flex was verified and validated in accordance with internally developed test plans.

VIII. Conclusions

In summary, the documentation provides evidence to make the reasonable conclusion that:

- The intended uses for the subject and predicate devices are the same.
- The indications for uses for the subject and predicate devices are substantially equivalent raising no new questions of safety or effectiveness.
- The functionality of the subject and predicate devices are substantially equivalent raising no new questions of safety or effectiveness.
- In the area of safety, the Scanmate Flex is shown to be as safe as the predicate devices for hazards of EMI, acoustic output, and biocompatibility raising no new questions of safety or effectiveness.
- In the area of effectiveness, the Scanmate Flex provides essentially the same features as the predicate devices, along with a number of software enhancements. Thus, it is at least as effective as its predicate devices, raising no new questions of efficacy when compared to the predicate devices.

DGH Technology believes the comparisons above support the substantial equivalence of the Scanmate Flex, the subject device, to its predicate devices.