DGH TECHNOLOGY, INC.

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DGH Handheld Pachymeter 510(k) Summary

Submitter:	DGH Technology, Inc. 110 Summit Drive, Suite B Exton, PA 19341
Contact Person:	M. Luther Detweiler Vice President, Regulatory Affairs Phone: 610-594-9100 / Fax: 610-594-0390 E-mail: Lou@DGHKOI.com
Date summary prepared:	10/7/2003
Device trade name:	DGH 55 Handheld Pachymeter (Pachmate)
Device common name:	Ultrasound Pachymeter
Device classification name:	System, Imaging, Pulsed Echo, Ultrasonic
Legally marketed devices to which the device is substantially equivalent:	DGH 500 Ultrasonic Pachymeter (K920906A)
Description of device:	The DGH 55 is a handheld ultrasonic pachymeter that uses echo spike techniques to measure the thickness of the cornea.
Intended use of the device:	Corneal thickness measurements are useful for screening potential laser refractive surgery patients, glaucoma screening, and monitoring corneal swelling.
Technological characteristics:	The technological characteristics are unchanged from the predicate device. The new microprocessor and associated hardware, and the new software implement the same algorithmic approach as the predicate device. The changes represent technology updates without changing functionality.

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Performance tests:

The following tests were performed to demonstrate substantial equivalence:

- ☒ Comparative corneal thickness measurement tests
- ☐ Comparative water bath/phantom tests
- ☒ Comparative electronic calibration verification tests
- ☐ EN 60601-1: Medical electrical equipment – Part 1: General requirements for safety – IEC 601-1,
- ☐ EN 60601-1-2: Medical electrical equipment – Part 1: General requirements for safety. Collateral standard: Electromagnetic compatibility requirements and tests. IEC 60101-2, and
- ☐ IEC 60601-2-37: Medical electrical equipment Part 2 – 37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (Clause 42.3 tested under condition 2 only.)
- ☐ Acoustic Output Reporting per section 4.6 of FDA Document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued on September 30, 1997.

Conclusions:

The results of the performance tests demonstrate that the device is substantially equivalent to the legally marketed predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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DGH Technology, Inc.
% Mr. N. E. Devine, Jr.
Responsible Third Party
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K033385
Trade Name: DGH 55 Handheld Pachymeter (Pachmate)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasound pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Dated: October 7, 2003
Received: October 23, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the DGH 55 Handheld Pachymeter (Pachmate), as described in your premarket notification:

Transducer Model Number

DGH2006DET

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	P									
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: Above indication for use is for the DGH55 Handheld Pachymeter with the DGH2006DET Detachable Probe.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

...sion Sign-Off)

...sion of Reproductive, Abdominal,

...Radiological Devices

...k) Number K033385