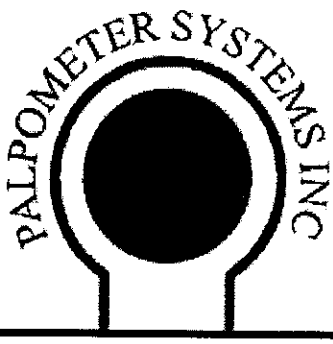
K060125



MAR 16 2006

PALPOMETER SYSTEMS INC
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510(k) Summary

Submitted by: Palpometer Systems Inc
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Tel: (250) 721-6502
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Contact: Lindsay Roach

Summary Prepared on January 6th, 2006

Trade Name: Sonic Palpometer

Common Name: palpometer

Classification Name: Miniature pressure transducer (per 21 CFR 890.1615)

Although there is no legally marketed predicate device for the Palpometer (as stated in the 513(g) device classification letter; reference: C030037, See **Appendix B**) these are devices in the same product code to which we are claiming some level of equivalence:

Device	**Applicant**	**510(k)**	**Decision Date**	Device website information
Pressore Monitor	Cleveland Medical Devices, Inc.	K954670	10/30/1995	http://www.clevemed.com/products/rehab/pm/index.html
micro-emed-system	novel electronics, inc.	K902967	09/17/1990	http://www.novel.de/pdf/flyer/eng/rls_eng.pdf http://www.novel.de/pdf/flyer/eng/emed_eng_ver2.pdf
Dynatron 2000	Dynatronics Corp.	K880912	03/15/1988	http://www.dynatronics.com/chronicpain/dynatron/ http://www.mdall.ca/ "dynatron"
emed-f-system	novel gmbh	K871690	05/15/1987	http://www.novel.de/pdf/flyer/eng/rls_eng.pdf
ZEUS MicroWrist Surgical System *	Intuitive Surgical Inc., Computer Motion	Approved Class 3 device		http://www.intuitivesurgical.com

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* The ZEUS MicroWrist Surgical System is not in the same Product Code as the Palpometer, however it uses the same Interlink FSR pressure sensor.

Description:
The Palpometer is a simple device that combines the fine motor and sensory attributes of manual examination with the precision measurements made with pressure gauges. By measuring the amount of pressure between the device and a soft tissue, the Palpometer standardizes pain response by controlling the pressure of the examiner's palpating finger. The Palpometer consists of a thin sensor, positioned on the palpating portion of the examiner's finger. The sensor changes its electrical resistance caused by varying the pressure exercised by the examining finger. The Palpometer beeps in a different tone as you pass through each programmable pressure threshold (of which there are five).

Intended Use:
The intended use of the Palpometer is to assess patient sensitivity to tactile stimulus by providing quantification of fingertip pressure, for tactile response procedures and treatments that use digital palpation.

Technological Characteristics:
The technological characteristics of the Palpometer are equivalent to several different devices. Like the Pressore Monitor, the Palpometer is a battery operated device that measures the amount of pressure between the device and soft tissue. The Palpometer uses a commercially available pressure sensor that converts mechanical inputs to analog signals similar to the Micro-emed-systems by novel electronics Inc. This sensor is the same one that is used in sensitive devices such as electronic infusion pumps, robotic controlled surgical systems (the Zeus MicroWrist Surgical System) and radiotherapy equipment to measure applied pressure. A programmed microprocessor, resistors, capacitors, reed switch, and piezoelectric speaker make up the other components. The level of pressure is indicated by the speaker that beeps at different tones depending upon the amount of pressure applied. The components are sealed inside a solid aluminum casing. The Palpometer is held in place on the finger by a Velcro strap.

Substantial Equivalence Data:
As there is no legally marketed predicate device (513(g) C030037, See **Appendix B**) a summary of the data and conclusions drawn from comparing the Palpometer to conventional means of pain measurement is included in the attached table.

STANDARD MEASUREMENTS OF PAIN COMPARED WITH THE SONIC PALPOMETER	SOURCE OF DATA	Results
Manual palpation • Tender joint scores in rheumatoid arthritis	Atkins, C. J. et al. (1992). *An electronic method for measuring joint tenderness in rheumatoid arthritis.* Arthritis & Rheum. 35:407-10	P. 409. Analysis of the modified electronic scores showed an intraobserver error of 0.12 compared with 0.2 for the conventional method. The correlation coefficient between the Palpometer and conventional measurements was increased from 0.62 to 0.78 when the less sensitive instrument was excluded, indicating a high level of construct validity.
• Tender point scores in headache	Bendtsen, L., Jensen, R., Jensen, N.K. and Olesen, J.R. (1995) *Pressure controlled palpation: A new technique which increases the reliability of manual palpation.* Cephalalgia 15, 205-210	P. 206. The sum of tenderness scores recorded by two different observers using conventional palpation differed significantly (P=0.0003) where results did not differ using pressure controlled palpation (P=0.89). A positive linear correlation between pressure and pain intensity was found (P=0.00006).
• Tender point scores in fibromyalgia	Bennet, R., Atkins, C.J., Zielinski, A., and Makosinski, A. (1996) *A miniaturized pain-measuring device called an electronic Palpometer worn on the examiner's finger links a pressure gauge to conventional manual palpation.* Collaborative study between University of Victoria with the Oregon Health Sciences University. Abstract in Proceedings of the 8th International Congress on Pain, August 1996, Vancouver, BC.	There was a good correlation (point estimates >0.7) between the Palpometer and conventional scores. Test retest measurements showed a similar correlation (>0.7).
Visual analog scale in fibromyalgia	Bendsten, L., Norregaard, J., Jensen, R., Olesen, J. (1997) *Evidence of qualitatively altered nociception in patients with fibromyalgia.* Arthritis & Rheum. 40:98	P. 99. In controls there is a linear relationship between pressure and pain in a double logarithmic plot in which the slope (ß) was 3.5 ± 0.66 log mm/log U j P<0.00001
Dolorimeters (algometers) • Handheld pain threshold meter (pain diagnostics and thermography NY) in headache	Neufeld, J.D., Holroyd, K.A., and Lipchik, G.L. (2000) *Dynamic assessment of abnormalities in central pain transmission and modulation in tension-type headache sufferers.* Headache. 40:142-151	P. 148. Similar responses before and after manipulation of cranial muscles with Dolorimeter threshold measurements and tenderness measurement with the Palpometer in headache prone patients. See Fig 3 & 4.
• Pressure Algometer Somedic to in tender myofascial muscles	Bendtsen, L., Jensen, R., Jensen, N.K. and Olesen, J.R. (1994) *Muscle palpation with controlled finger pressure: New equipment for the study of tender myofascial tissues.* Pain. 59, 235-239	P. 236. A pressure algometer Somedic was used to relate arbitrary units of the Palpometer to tone. In this fashion, a standard dolorimeter was used to calibrate the Palpometer.
• Chatillon in fibromyalgia	Puttick, M.P.E., et al. (1995) *Reliability and reproducibility of fibromyalgic tenderness: measurement by electronic and mechanical dolorimeters.* Journal of Musculoskeletal Pain. 3:3-14	P. 4. ConstructValidity is demonstrated by similar response to tender point measurements with the dolorimeter at highly reproducible measurements with Palpometer show lesser but still good reliability.
• Chatillon in fibromyalgia	Atkins, C.J., andZielinski, A. (1997) *Comment on Article by Puttick, M.P.E., et al. Reliability and reproducibility of fibromyalgia tenderness, measurement by electronic and mechanical dolorimeters.* Journal of Musculoskeletal Pain. 5:127-131	Atkins and Zielinski comment on the Puttick article indicating that inconsistency in technique and failure to secure the sensor the examining finger resulted in sub-optimal performance by the Palpometer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

Palpometer Systems, Inc.
c/o Intertek Testing Services
Mr. Daniel W. Lehtonen
Staff Engineer – Medical Devices
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K060125
Trade/Device Name: Sonic Palpometer
Regulation Number: 21 CFR 890.1615
Regulation Name: Miniature pressure transducer
Regulatory Class: I
Product Code: IKE
Dated: March 2, 2006
Received: March 3, 2006

Dear Ms. Lehtonen:

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.

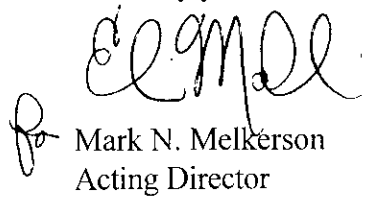
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 letter will allow you to begin marketing your device as described in your Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060125

Device Name: Sonic Palpometer

Indications for Use:

The intended use of the Sonic Palpometer is to assess patient sensitivity to tactile stimulus by providing quantification of fingertip pressure, for tactile response procedures and treatments that use digital palpation.

Prescription Use ___✓____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060125