MAY 25 2007

SAFETY & EFFECTIVENESS DATA SUMMARY

Submitters Name, Address:	Terumo Corporation 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo, 151-0072, Japan
Manufacturing site name, address:	Suruga factory of Terumo Corporation 150, Maimaigi-cho, Fujinomiya-shi, Shizuoka-pref 418-0015, Japan
Submission Correspondent:	Lyle Howard Corporation 106 East 5th Avenue Mount Dora, Florida 32757 USA Attention: Lynette Howard 352.383.8333
Classification Name:	Noninvasive Blood Pressure Measurement System
Common / Usual Name:	Blood Pressure Monitor
Proprietary Name:	Terumo Digital Blood Pressure Monitor ES-H55A
Classification:	Class II, Reg. # 870.1130, DXN, Cardiovascular Devices Panel
Performance Standards:	21 CFR Part 898 and 1010

Substantial Equivalence:

The legally marketed devices to which substantial equivalence is demonstrated are A & D Lifesource, UA-704 Digital Blood Pressure Monitor (K032499) and the American Diagnostic Corporation e-sphyg digital Aneroid Blood Pressure Instrument (K962655).

The subject device is substantially equivalent with the predicate devices in the intended use, design, principle of operation, i.e., oscillometric/auscultatory method, specifications and performance.

The principal difference between the subject device and predicates is the intended population. For Terumo Digital Blood Pressure Monitor ES-H55A, the intended population is Pediatric (age 3 and above) except for neonate and infant, and Adult, while the intended population for predicates is Adult. By performing the bench test and clinical evaluation incl. pediatric patients in accordance with ANSI/AAMI Standard SP10:2002, Electronic or Automated Sphygmomanometers, it is clear that the difference raises no new questions with respect to either safety or effectiveness.

Testing conducted or standards applied to assure safety and effectiveness includes but is not limited to:

Clinical Performance and Accuracy: ANSI/AAMI Standard SP10-2002, Electronic or Automated Sphygmomanometers, approved October 28, 2002.

Electrical safety: IEC60601-1 2nd as amended

Electromagnetic Compatibility: IEC 60601-1-2, 2001 with test procedures according to IEC 61000-4-2, 2001; IEC 61000-4-3, 2002; IEC 61000-4-8, 2001.

Description of the new device:

The Terumo Digital Blood Pressure Monitor ES-H55A is a non-invasive device to measure patient's blood pressure by electrically detecting and amplifying the pulse wave and pressure signal obtained from the inside of the cuff. As an automated Blood Pressure Monitor, it measures the systolic and diastolic blood pressure and pulse rate using Oscillometric method. Also as a manual sphygmomanometer (pressure gauge), it displays the pressure values.

Intended Use:

The Terumo Digital Blood Pressure Monitor ES-H55A is a non-invasive device to measure blood pressure at upper arm for pediatric(age 3 and above) except for neonate and infant, and adult, using an appropriate sized cuff. It measures systolic and diastolic blood pressures and pulse rate using oscillometric method, also it serves as a manual sphygmomanometer using a stethoscope. It is intended for professional use.

Safety and Efficacy Information:

The Terumo Digital Blood Pressure Monitor ES-H55A is well recognized as being safe and effective for the stated intended use. The TerumoDigital Blood Pressure Monitor ES-H55A has the same operating principals and intended uses as the predicate Blood Pressure Monitor systems already in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2007

Terumo Corporation
c/o KEMA Quality B.V.
Patricia L. Murphy
4377 Country Line Rd.
Chalfont, PA 18914

Re: K071075
Trade/Device Name: Terumo Digital Blood Pressure Monitor ES-H55A
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 11, 2007
Received: May 14, 2007

Dear Ms. Murphy:

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 240-276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071075

Device Name: TERUMO Digital Blood Pressure Monitor ES-H55A

Indications for Use:

The TERUMO digital blood pressure monitor ES-H55A is a non-invasive device to measure blood pressure at upper arm for pediatric(age 3 and above) except for neonate and infant, and adult, using an appropriate sized cuff. It measures systolic and diastolic blood pressures and pulse rate using oscillometric method, also it serves as a manual sphygmomanometer using a stethoscope. It is intended for professional use.

Prescription Use __x_____ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Symmons

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071075