JUN 2 3 2000

K993623

ALLEN MEDICAL INSTRUMENTS CORP.
505 Superior Avenue
Newport Beach, CA 92663
(~~714~~ 949) 646-3215
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510(K) SUMMARY

DATE SUMMARY PREPARED: 10/22/99

1. **Submitter's Identification:**

   Mrs. Judith Allen
   Vice President
   Allen Medical Instruments Corp.
   505 Superior Avenue
   Newport Beach, CA 92663

2. **Name of the Device:**

   GEMINI E Electronic Stethoscope

3. **Predicate Device Information:**

   Simulscope Bedside Auscultation System

4. **Device Description:**

   An electronic stethoscope utilizing conventional stethoscope components but amplifying auscultated sounds by means of a 3 volt electronic circuit. An output jack is provided for headphone use. The stethoscope is controlled by a single button which turns the unit on and adjusts the amplitude through four levels.

5. **Indications for use:**

   a) **Normal auscultation of the cardiovascular system, pulmonary system or gastro-intestinal system by a healthcare professional.**

   b) **Normal auscultation as above by a healthcare professional who wears hearing aids.**

   b) **To allow four other listeners [e.g. students] to listen together with a healthcare professional.**

6. **Discussion of non-clinical tests performed for determination of substantial equivalence.**

   Emissions testing was conducted by Acme Laboratories in Acme, Washington. Safety testing in accordance with government requirements was conducted by Intertek Testing Services in Laguna Niguel, California.

7. **Discussion of clinical tests performed:**

Non-applicable.

8. **Conclusions:**

Based on the above, the GEMINI E stethoscope is substantially equivalent to the Simulscope Bedside Auscultation System in it's applications. Safety has been established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2000

Ms. Judith Allen, Vice President
Allen Medical Instruments Corp.
505 Superior Ave.
Newport Beach, CA 92663

Re: K993623
Trade Name: GEMINI E Electronic Stethoscope
Regulatory Class: II (Two)
Product Code: 74 DQD
Dated: May 18, 2000
Received: May 22, 2000

Dear Ms. Allen:

We have reviewed your Section 510(k) 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

INDICATIONS FOR USE

1) **Normal auscultation of the cardiovascular system, pulmonary system or gastro-intestinal system by a health care professional.**

2) **Normal auscultation as above by a health care professional who wears hearing aids.**

3) **To allow four other listeners (e.g. students) to listen together with a health care professional.**

for Mark N Milhorn

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993623