DEC 10 1999

K991756

510(K) Summary

Sponsor.
Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581

Device.
3 Channel Knee Electronic Amplified Stethoscope
(Electronic Stethoscope with Goniometer Attachment)

Classification Name.
Stethoscope, Electronic-Amplified (21 CFR 888.1875) / Goniometer (21 CFR 888.1500)

Device Description.
The device is intended for use by a physician as a noninvasive tool to amplify and record distinct sounds (vibrations) within the three compartments (medial, lateral, and patellar) of the knee joint.

The 3 Channel Knee Stethoscope System consists of three transducers, or sensors, to pick up the vibrations (sound) from three locations on the knee. The transducers are plugged into an amplifier box that is connected to a standard personal computer installed with Windows 3.1, or later version. A goniometer attachment is also plugged into the amplifier box. The system generates a metronome arrow that moves on the computer monitor screen (3 seconds per flex/extend cycle). The patient watches the arrow to pace the speed and direction of knee flexion and extension, while staying "in sync" with the metronome to maintain a 3 second cycle. Motion and sound vibrations are amplified, recorded in graph form, and stored in a patient database.

Potential Risks.
A potential risk is the device or its software malfunctions in such a way that it provides inaccurate information to a physician. However, should such a malfunction occur, the risk is minimal to the patient since the device is not intended to a means of diagnosis, but an adjunct to diagnostic tools used by the physician. The device is intended to help the physician to confirm the diagnosis and to identify the location and severity of the injury or disease condition within the knee joint. No energy is applied to the patient by the device.

Substantial Equivalence.

The purpose of a stethoscope, electronic amplified is to magnify any vibrations (sounds) and make them more discernable to the clinician. The 3 Channel Knee Electronic Amplified Stethoscope is equivalent to 3M Littmann Electronic Stethoscope based upon its intended use for the amplification of faint heart, lungs, and **other body sounds** as well as normal auscultation and selective frequency filtering. In addition, it is substantially equivalent to the Transmedica Model 100 Digital Electronic Stethoscope in that it uses multiple piezzo-electric transducers and a general purpose digital computer to process, store, and display the sound recordings. Please note that stethoscopes are a listening tool for the physician, and have been used historically to amplify a wide variety of soundswithin the human body, including human joints.

The 3 Channel Knee Electronic Amplified Stethoscope helps the physician to better visualize the location of the vibration. There are no interpretive or other diagnostic capabilities currently claimed for this device. However we intend to initiate further testing to determine if interpretive capability is possible.

Published Papers

1. ML Chu, IA Gradisar, MR Railey, and GF Bowling (1976); An Electro-Acoustical Technique for the Detection of Knee Joint Noise. *Medical Research Engineering*, Vol.12, No.1, 18-20.

2. WG Kernohan, DE Beverland, GF McCoy, SN Shaw, RGH Wallace, GC McCullagh, RAB Mollan (1986); The Diagnosis Potential of Vibration Arthography. *Clinical Orthopaedics and Related Research*, Number 210, September: 106-12.

3. WG Kernohan, DE Beverland, GF McCoy, A Hamilton, P Watson, R Mollan (1990); Vibration Arthrometry. *Acta Orthop Scand*, 61(1):70-79.

4. GF McCoy, JD McCrea, DE Beverland, WG Kernohan, RAB Mollan (1987); Vibration Arthrography as a Diagnostic Aid in Diseases of the Knee. *The Journal of Bone and Joint Surgery*, Vol.69B, No.2, March, 288-93.

5. RAB Mollan, GW Kernohan, and PH Watters (1983); Artefact Encountered by the Vibration. *Journal of Biomechanics*, 16(3): 193-9.

6. RGH Wallace, RAB Mollan, WG Kernohan; Preliminary report on a New Technique to Aid Diagnosis of Some Disorders Found in Hands. (1985); *The Journal of Hand Surgery*, Vol. 10B, No.2: June: 269-72.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1999

Ms. Lonnie Witham
Senior Regulatory Affairs Specialist
Biomet Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K991756
3 Channel Knee Electronic Amplified Stethoscope
Regulatory Class: II (two)
Product Code: DQD
Dated: September 15, 1999
Received: September 16, 1999

Dear Ms. Witham:

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 Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(K) NUMBER K991756

DEVICE NAME: 3 CHANNEL KNEE ELECTRONIC AMPLIFIED STETHOSCOPE

INDICATIONS FOR USE:

The 3 Channel Knee Electronic Amplified Stethoscope is intended for use by a physician as a noninvasive tool to amplify and record distinct sounds (vibrations) within the three compartments (medial, lateral, and patellar) of the knee joint.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991756