DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mayo Foundation for Medical Education and Research
% Mr. Keith Barritt
Fish & Richardson, P.C.
1425 K Street Northwest
11th Floor
Washington, District of Columbia 20005

SEP 11 2006

Re: C060169
Device Name: Mayo Interactive Breath Hold Monitor
Dated: July 19, 2006
Received: July 20, 2006

Dear Mr. Barritt:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the Mayo Interactive Breath Hold Monitor. Based on the information provided in your submission, we believe the Mayo Interactive Breath Hold Monitor falls within Title 21 of the Code of Federal Regulations (CFR) 882.5050, Biofeedback device (Product Code – HCC). A biofeedback device is a Class II type device, exempt from the premarket notification [510(k)] requirements of the Act, subject to the limitations to the exemption found in 21 CFR 882.9.

Please be advised that our response to your 513(g) request for information does not mean that the Food and Drug Administration (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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Please be advised that Title 21 Code of Federal Regulations, Part 807, Subparts A-D, requires all establishments, whether foreign or domestic, that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into or distribution in the U.S. to register and list with the FDA. If you have any questions regarding the registration and listing requirements, please call (240) 276-0132.

Section 513(g) of the Act requires the agency to provide information about the regulatory requirements applicable to a particular type of device. The response represents my best judgment about how the product would be regulated, based upon our review of the information you have provided, including your description of the product and its intended use. My response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution.

If you have any questions regarding this letter, please contact Mr. Neil Ogden, Chief, General Surgical Devices Branch, at (301) 594-1307 or for general questions please contact 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,

Miriam C. Provost

Miriam C. Provost, Ph. D.
Deputy Director for Engineering
and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health