

SECTION 20: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

20.1 SUBMITTER INFORMATION

- a. Company Name: BioAnalogics, Inc.
- b. Company Address: 9000 SW Gemini
Beaverton, OR 97008
- c. Company Phone: (503) 626-8000
- d. Contact Person: Richard Wooten
President
BioAnalogics, Inc.
- e. Date Summary Prepared: July 1, 1996

20.2. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: Edema System
- b. Classification Name: Impedance Plethysmograph

20.3 IDENTIFICATION OF PREDICATE DEVICE

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
BioAnalogics	Consultant™ Body Composition Analyzer	K871040	June 5, 1987

20.4 DEVICE DESCRIPTION

The Edema System is a device that measures body composition in terms of edema of the extremities. Specialized software monitors the impedance values taken from

the patient along with additional biological data. The device is connected to the patient via non-invasive electrode sensors and placement leads. The device operates off of a 9-volt battery and is fully portable. The addition of an IBM compatible computer workstation is required to run the accompanying software program. A complete description of the device has been included in Section 5 of this submission.

20.5 SUBSTANTIAL EQUIVALENCE

The Edema System is substantially equivalent to the Consultant™ Body Composition Analyzer in terms of its intended use as a device to provide the physician or health care professional with impedance information that can be utilized for therapeutic and preventative instruction in treating health disorders.

The fundamental technical characteristics are similar to those of the predicate device and are listed on the comparison chart provided in this 510(k) submission. Differences that exist between these systems relate to the software program which has been described in Section 18.

20.6 INTENDED USE

The Edema System is a device intended to provide information which the physician or health care professional can utilize for therapeutic and preventative instruction in treating edema of the extremities.

20.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Edema System and the predicate device has been provided in this submission. Finished product

specifications, schematic drawings, as well as a complete description of the software characteristics have been provided.

20.8 PERFORMANCE DATA

The Edema System has been demonstrated to perform as intended with accuracy and repeatability. Complete results of performance testing of the Edema System have been included in Sections 14 and 17 of this submission.

20.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 1997

Mr. Rich Wooten
BioAnalogics, Inc.
7909 W.W. Cirrus Drive
Beaverton, Oregon 97008

Re: K962783
Edema System
Regulatory Class: II (two)
Product Code: 74 DSB
Dated: August 20, 1997
Received: August 22, 1997

Dear Mr. Wooten:

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 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.

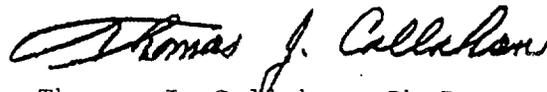
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

To Be Assigned By FDA : K962783

Device Name:

Edema System

Indications For Use:

The Edema System is a device intended to provide information which the physician or health care professional can utilize for therapeutic and preventative instruction in treating increased extremity edema.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

A. A. Ciarkowski

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

K962783

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)