MAY 2 2013

1 Submitter Information

Owner:	seca gmbh & co. kg.
Address:	Hammer Steindamm 9 – 25 22089 Hamburg Germany
Internet:	www.seca.com
Contact:	Djavaneh Blalaie – Quality Management
Telephone Number:	+49 40 20 00 00 – 259
FAX Number:	+40 40 20 00 00 – 3259
E-mail:	djavaneh.blalaie@seca.com
Date prepared:	April 22, 2013

2 Device Name

Common Device Name:	Body Composition Analyzer
Trade names:	seca medical Body Composition Analyzer 514, seca mBCA 514, seca mBCA, seca 514
Device Class:	Class II
Classification Code:	MNW – Analyzer, Body Composition
Regulation number:	21 CFR 870.2770

3 Predicate Device

BioSpace InBody 720

Common Device Name:	Body fat meter
Trade names:	Biospace Body Composition Analyzer, Model Inbody 720
Device Class:	Class II
Classification Code:	MNW – Analyzer, Body Composition
Regulation number:	21 CFR 870.2770
510(k) number:	K052646

4 Device Description

The seca mBCA 514 is a scale and impedance plethysmograph body composition analyzer for estimation of the body composition of individuals based on the Bioelectrical Impedance Analysis (BIA). The device measures bioelectrical impedance values by means of multi frequency,

segmental measurements (right arm, left arm, trunk, right leg, left leg, right body side and left body side).

5 Intended Use

The seca mBCA 514 measures body Weight and records body Height for calculation of Body Mass Index (BMI), Resting Energy Expenditure (REE) and Total Energy Expenditure (TEE) to monitor growth process and weight changes in individuals of all ages.

In healthy individuals aged 18 years and older the device also measures body impedance (Reactance Xc and Resistance R) for estimation of body composition. Estimation of body composition includes Total Body Water (TBW), Intra Cellular Water (ICW), Extra Cellular Water (ECW), Lean Soft Tissue (LST), Fat-Free Mass (FFM), Fat Mass (FM), Fat Mass Indices (FMI and FMMI), Skeletal Muscle Mass (SMM), Bioelectrical Impedance Vector Analysis (BIVA), Energy stored in body (Ebody) and Phase Angle (Φ).

The seca mBCA 514 can be used in conjunction with the optional PC software accessory seca analytics 115 for data management, calculations and display of information.

6 Safety and Effectiveness Comparison

The results of bench and clinical testing demonstrate that the seca mBCA 514 is as safe and effective as the predicate device. Impedance raw data measurements (Impedance, Resistance, Reactance, and Phase Angle) and measurements of Weight were compared against measurements made by the Biospace InBody 720 (K052646). Estimation of Total Body Water (TBW) was compared against the deuterium oxide dilution method. Estimation of Extra Cellular Water (ECW) was compared against the sodium bromide dilution method. Estimation of Lean Soft Tissue (LST) was compared against measurements obtained from the GE Lunar iDXA Bone Densitometer (K052581). Fat-Free Mass (FFM) was estimated by applying the four compartment model, which incorporates measurements from the GE Lunar iDXA Bone Densitometer (K052581), the BOD POD Sonamet Body Composition Analyzer (K060848), and the deuterium oxide dilution method.

7 Conclusion

The differences with the predicate devices and methods are sufficiently minor to establish substantial equivalence, and do not impact the safety or the effectiveness of the device when used as labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2013

seca gmbh & co. kg
% Mr. Seth A. Mailhot
Special Counsel
Sheppard Mullin Richter & Hampton LLP
13001 Street, NW, 11th Floor East
WASHINGTON DC 20005-3314

Re: K122388
Trade/Device Name: seca mBCA 514
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: April 24, 2013
Received: April 25, 2013

Dear Mr. Mailhot:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122388

Device Name: seca mBCA 514

Intended Use:

The seca mBCA 514 measures body Weight and records body Height for calculation of Body Mass Index (BMI), Resting Energy Expenditure (REE) and Total Energy Expenditure (TEE) to monitor growth process and weight changes in individuals of all ages.

In healthy individuals aged 18 years and older the device also measures body impedance (Reactance Xc and Resistance R) for estimation of body composition. Estimation of body composition includes Total Body Water (TBW), Intra Cellular Water (ICW), Extra Cellular Water (ECW), Lean Soft Tissue (LST), Fat-Free Mass (FFM), Fat Mass (FM), Fat Mass Indices (FMI and FMMI), Skeletal Muscle Mass (SMM), Bioelectrical Impedance Vector Analysis (BIVA), Energy stored in body (E_{body}) and Phase Angle (Φ).

The seca mBCA 514 can be used in conjunction with the optional PC software accessory seca analytics 115 for data management, calculations and display of information.

Prescription Use ____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X__ (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)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122388