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

AB Mando
% Mr. Daniel Olivier
Certified Compliance Solutions, Inc.
11665 Avena Place
Suite 203
San Diego, California 92128

November 6, 2018

Re: DEN070014 (K063817)
Mandometer
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 882.5060
Regulation Name: Conditioning tool for eating disorders
Regulatory Classification: Class II
Product Code: OBV
Dated: June 19, 2007
Received: June 20, 2007

Dear Mr. Olivier:

This letter corrects our classification letter dated March 31, 2011.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Mandometer, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

> The Mandometer® device aids in the treatment of eating disorders. Mandometer® monitors a patient's eating rate and provides feedback to the patient on learning normal eating behavior and normal feelings of satiety. Mandometer® requires use in conjunction with an established Mandometer treatment program.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Mandometer, and substantially equivalent devices of this generic type, into class II under the generic name, conditioning tool for eating disorders.

FDA identifies this generic type of device as:

> **Conditioning tool for eating disorders.** A conditioning tool for eating disorders is a prescription device that non-invasively measures the mass of food eaten during a meal and provides feedback in the form of eating rate, patient satiety, and eating pattern information to the patient.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on May 24, 2007, automatically classifying the Mandometer in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On June 20, 2007, FDA received your De Novo requesting classification of the Mandometer into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Mandometer into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the De Novo request, FDA has determined that the Mandometer indicated for aiding in the treatment of eating disorders by monitoring a patient's eating rate and providing feedback to the patient on learning normal eating behavior and normal feelings of satiety, can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Ineffective treatment leading to worsening condition of the patient, progression of the disease, and/or delay of alternative treatments	Non-clinical performance testing, Software validation, verification and hazard analysis Labeling
Adverse tissue reaction	Biocompatibility evaluation
Electrical shock or burns	Electrical safety testing, Electromagnetic compatibility (EMC) testing, and Labeling

In combination with the general controls of the FD&C Act, the conditioning tool for eating disorders is subject to the following special controls:

1. Non-clinical performance testing must demonstrate
   a. Device measurement accuracy and repeatability; and
   b. Device feedback accuracy.

2. Software verification, validation, and hazard analysis must be performed.

3. The patient-contacting components of the device must be demonstrated to be biocompatible.

4. Performance testing must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

5. Labeling and patient labeling must be provided which includes the following:
   a. Information identifying and explaining how to use the device and its components; and
   b. Information on how the device operates and the typical course of treatment.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the conditioning tool for eating disorders they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Michael Hoffmann at 301-796-6476.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health