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

June 14, 2016

Aspire Bariatrics, Inc.
Monica Ferrante
VP Regulatory & Quality
3200 Horizon Drive
Suite 100
King Of Prussia, Pennsylvania 19406

Re: P150024
Trade/Device Name: AspireAssist®
Filed: July 10, 2015
Amended: July 27, 2015; August 20, 2015; September 18 and 28, 2015;
October 26, 2015, and January 20, 2016
Product Code: OYF

Dear Monica Ferrante:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the AspireAssist. This device is intended to assist in weight reduction of obese patients. It is indicated for use in adults aged 22 or older with a Body Mass Index (BMI) of 35.0-55.0 kg/m^2 who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for a long-term duration of use in conjunction with lifestyle therapy and continuous medical monitoring. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that this restriction on sale and distribution is necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at three years for the A-tube and six months for the remaining device components. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. Separate PAS Progress Reports must be submitted for each study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. Two (2) copies of each report, identified as an "ODE Lead PMA Post-Approval Study Report" or "OSB Lead PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

1. ODE Lead PMA Post-Approval Study - Extended Follow-up of the Premarket Cohort (PATHWAY Clinical Trial): The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The Extended Follow-Up Study is a multicenter, single-arm prospective, active surveillance study designed to gather long-term data on the incidence, duration, and severity of adverse events, weight loss, compliance with AspireAssist therapy, impact of AspireAssist therapy on eating behavior and the effectiveness and safety outcomes after device removal. This study will continue to follow patients from the PATHWAY pivotal study for up to five years post implantation who maintain $\geq$ 10 % absolute weight loss (relative to baseline) at each annual visit. Any subject that has the device explanted will be followed for two years post device explantation. A total of 46 subjects are available for the extended follow-up study and will be invited to participate in the extended follow-up PAS.

There are no pre-defined safety and efficacy endpoints for this active surveillance study. While the device is implanted, the safety of the device will be evaluated by: 1) the incidence of device-related, procedure-related, and therapy-related adverse events; 2) the incidence of device-related or unrelated serious adverse events, including unanticipated adverse device effects; and 3) development of adverse eating behaviors as measured by the Eating Disorder Examination (EDE) and the Questionnaire on Eating and Weight Patterns – Revised (QEWP-R). The efficacy of the device while implanted will be assessed by percent excess weight loss (%EWL) and total body loss (%TBL). Other efficacy study endpoints while the device is implanted include the change in obesity-related comorbidities (blood pressure, lipid levels, triglycerides, HbA1c) and change in medication. After the device is removed, patients will be followed for two years. During the first six months patients will be monitored for fistula closure, weight loss, and adverse events and subjects with diabetes will be monitored for HbA1c, blood glucose, and diabetes medications. For six to 24 months after device removal subjects will be followed for weight loss, adverse events, psychological assessment, lipids and HbA1C.

2. OSB Lead PMA Post-Approval Study - AspireAssist Post Approval Study: The Office of Surveillance and Biometrics (OSB) will have the lead for studies initiated after device approval. This study will be conducted as per protocol provided interactively on March 23, 2016, Version P016-001V Revision B.

   The purpose of this post-approval study is to assess the safety and effectiveness of the AspireAssist device with regard to: compliance with AspireAssist therapy and transient weight-loss following the therapy, impact of AspireAssist therapy on eating behavior, incidence, duration and severity of adverse events (in particular, infection and stoma-related issues) and the effectiveness and safety outcomes after device explant. This is a new enrollment study that will include subjects who are 22 years of age or older, with a body mass index (BMI) of 35.0-55.0kg/m2, who meet the inclusion and exclusion criteria per approved protocol, and who agree to participate in the study. Study subjects will be followed for five (5) years post-implant. Additionally, subjects who have the device removed will be followed for two (2) years post-explant.

   An exact binomial test will be used to assess if the serious adverse event rate at 5 years is less than 7%. A total of 323 subjects will be consecutively enrolled, from 15 sites (15-35 subjects per site). Five years data will be available on 259 subjects, which should provide 80% power to reject the null hypothesis of the study, assuming a serious adverse event (SAE) rate of 3% (observed in premarket studies).

   The primary safety endpoint of this post-approval study assesses the hypothesis that the five-year serious adverse event (as defined by the Safety Adjudication Committee) rate is less than 7%.

   The study will also assess the following secondary effectiveness endpoints:
   1. Compliance with appropriate use of the AspireAssist system (Weight loss % Excess Weight Loss (EWL) and % Total Body Loss (TBL), and connector counts will be

assessed). Excess weight will be determined from ideal body weights based on a BMI = 25kg/m^2
2. Percentage of patients achieving a 25%EWL
3. Percentage of patients who have a positive or negative change in medications related to comorbidities (hypertension, diabetes, and dyslipidemia)

And the following secondary safety endpoints:
1. Percentage of patients with AEs related to eating disorders
2. Five-year rate of incidence, duration and severity of AEs related to stoma issues including infection (bacterial or fungal) and granulation tissue

Continuous outcomes will be provided through descriptive statistics with 95% confidence intervals, and all rates will be calculated and presented with exact 95% confidence intervals.

Interim reports will be provided every six months for the first two years of the study, and annually thereafter.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA. In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm).

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise become aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health

PMA Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Martha Betz, Ph.D. at 301-796-2844 or Martha.Betz@fda.hhs.gov.

Sincerely yours,

William H. Maisel -S

William H. Maisel, MD, MPH
Deputy Center Director for Science
Center for Devices and Radiological Health