



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

July 25, 2014

Ms. Naomi Gong  
Sr. Regulatory Affairs Project Manager  
MicroVention, Inc.  
1311 Valencia Avenue  
Tustin, CA 92780

Re: H130005

HUD Designation # 09-0222

Low-Profile Visualized Intraluminal Support Device (LVIS and LVIS Jr.): Models 212517-LVIS, 212525-LVIS, 213015-LVIS, 213025-LVIS, 213041-LVIS, 214035-LVIS, 214049-LVIS, 172516-LVISJ, 172524-LVISJ, 172530-LVISJ, and 172537-LVISJ

Filed: October 28, 2013

Amended: January 29 and February 5, 2014

Procode: NJE

Dear Ms. Gong:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your humanitarian device exemption (HDE) application for the Low-Profile Visualized Intraluminal Support Devices (LVIS and LVIS Jr.). This device is indicated for use with bare platinum embolic coils for the treatment of unruptured, wide-neck (neck  $\geq$  4 mm or dome to neck ratio  $<$  2 mm), intracranial, saccular aneurysms arising from a parent vessel with a diameter  $\geq$  2.5 mm and  $\leq$  4.5 mm. We are pleased to inform you that your HDE is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale, distribution, and use of this device are limited to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) under the authority of section 515(d)(1)(B)(ii) of the FD&C Act. In addition, in order to ensure the safe use of the device, FDA has further restricted the device within the meaning of section 520(e) of the FD&C Act under the authority of section 515(d)(1)(B)(ii) of the FD&C Act insofar as (1) the labeling shall specify the training requirements for practitioners who may use the device as approved in this order and (2) the sale, distribution, and use must not violate sections 502(q) and (r) of the FD&C Act.

Continued approval of this HDE is contingent upon the submission of periodic reports, required under 21 CFR 814.126, at intervals of one year (unless otherwise specified) from the date of approval of the original HDE. Two (2) copies of this report, identified as "Annual Report" and bearing the applicable HDE 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 814.126.

In addition to the above, an HDE holder is required to maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing institutional review boards (IRBs), as well as any other information requested by a reviewing IRB or FDA.

Before making any change affecting the safety or effectiveness of the device, you must submit an HDE supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39 except a request for a new indication for use of for a humanitarian use device (HUD). A request for a new indication for use for an HUD shall comply with the requirements set forth in 21 CFR 814.110 which includes obtaining a new designation of HUD status for the new indication for use and submission of an original HDE application in accordance with §814.104. The application for the new indication for use may incorporate by reference any information or data previously submitted to the agency.

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 becomes 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 [www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm](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 [www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm](http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm).

This device may not be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device. See section 520(m)(3) of the Federal Food, Drug, and Cosmetic Act.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of an HDE. 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.

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 HDE by making available a summary of the safety and probable benefit of the device upon which the approval was based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm>. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the HDE 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 requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the FD&C Act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this HDE submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when HDE applicants include with their submission of the final printed labeling 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.

Any information to be submitted to FDA regarding this HDE should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above HDE number to facilitate processing:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
HDE Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Daryl Kaufman, M.A. at 301-796-6467 or [Daryl.Kaufman@fda.hhs.gov](mailto:Daryl.Kaufman@fda.hhs.gov).

Sincerely yours,

**Carlos L. Peña -S**

Carlos L. Peña, Ph.D., M.S.

Director

Division of Neurological

and Physical Medicine Devices

Office of Device Evaluation

Center for Devices and Radiological Health