



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Ms. Claartje Beks-Ypma
VP Operations
Elana, Inc.
10480 Little Patuxent Parkway
Suite 400
Columbia, MD 21044

MAR 10 2011

Re: H080005

HUD NUMBER: 03-0108

Elana Surgical Kit_{HUD}

Filed: December 5, 2008

Amended: January 16, March 6, May 26, and December 9, 2009; February 22, March 2, July 28, August 2, September 17, September 20, and December 9, 2010; and February 11, 2011

Product Code: MCW

Dear Ms. Beks-Ypma:

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 Elana Surgical Kit_{HUD}. This device is indicated for the Elana Surgical Kit_{HUD}, when connected to the Spectranetics Xenon-Chloride Laser Model CVX-300, for creating arteriotomies during an intracranial vascular bypass procedure in patients 13 years of age or older with an aneurysm or a skull base tumor affecting a large (> 2.5 mm), intracranial artery that failed balloon test occlusion, cannot be sacrificed, or cannot be treated with conventional means due to local anatomy or complexity. CDRH is pleased to inform you that your HDE is approved subject to the enclosed "Conditions of Approval." You may begin commercial distribution of the device after you have submitted an amendment to this HDE with copies of the approved labeling in final printed form.

In addition to the postapproval requirements in the enclosure, the postapproval reports must include the following information:

You have also agreed to conduct a post approval study that collects information about the Elana Surgical Kit_{HUD} performance in a post approval setting with special attention to flap retention rate, mortality and stroke.

The study will be performed in the form of a registry that includes all patients who receive the procedure. This means that information about the Elana Surgical Kit_{HUD} will

be collected on specific forms to monitor how this surgical kit is performing in a post approval setting. A specific focus will be on overall flap retention rate, mortality and stroke. Information will be collected pre-operatively, during the operation and at one post operative follow up >25 days. The latter follow up is required to collect the modified Rankin score (mRs) to be able to define non-fatal stroke. The primary endpoint for this registry will be flap retention. You agreed to collect data based upon the following sample size calculations: A total of 80 device uses will provide 80% power for showing the flap retention rate does not exceed 38% under the assumption that the true rate is 22%. The true flap retention rate of 22% is based on the results of an IDE study on 37 device uses. Mortality and non-fatal strokes will be recorded but no statistical analyses beyond summarization of these events will be reported. The protocol for this study was developed through interactive review with the Office of Surveillance and Biometrics prior to this approval order and submitted as H080005/A010.

Any changes to the approved protocol must be submitted as an HDE supplement clearly labeled as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please reference the HDE number above to facilitate processing. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2). You will submit reports on a 6-month schedule during the first two years and annually thereafter until the post-approval study is completed. The reports should clearly be identified as a Post-Approval Study Report.

Please be advised that the results from these studies should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of an HDE Supplement.

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 act) under the authority of section 515(d)(1)(B)(ii) of the 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 act under the authority of section 515(d)(1)(B)(ii) of the 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 act.

FDA wishes to remind you that failure to comply with any postapproval requirement constitutes a ground for withdrawal of the HDE. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

The Pediatric Medical Device Safety and Improvement Act of 2007 allows HDEs indicated for pediatric use and approved on or after September 27, 2007, to be sold for profit as long as the number of devices distributed in any calendar year does not exceed the annual distribution number (ADN). This device is indicated for use in pediatric patients and, based on the information provided in your HDE application, the ADN for this device is determined to be 1000. As stated in section

520(m)(8) of the Act, the agency's Pediatric Advisory Committee will annually review all HUDs intended for use in pediatric patients that are approved on or after September 27, 2007, to ensure that the HDE remains appropriate for the pediatric populations for which it is granted. You must immediately notify the agency by submitting an HDE report whenever the number of devices shipped or sold in a year exceeds the ADN. For additional information on the ADN, please see the "Draft Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff – Humanitarian Device Exemption (HDE) Regulation: Questions and Answers" at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110194.htm>.

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/cdrh/ode/hdeinfo.html>. 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 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
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Kristen A. Bowsher, Ph.D. at Kristen.Bowsher@fda.hhs.gov or (301) 796-6448.

Sincerely yours,

A handwritten signature in black ink that reads "Christy Foreman MD PhD for". The signature is written in a cursive, flowing style.

Christy Foreman
Acting Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure