DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	04/06/2010 - 04/12/2010* FEI NUMBER 3003079393

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert A. Stern, President

FIRM NAME	STREET ADDRESS
Micrus Endovascular Corporation	821 Fox Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95131-1601	Medical Device Maufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, Product Complaint #15889 was received on 3/8/10 the physician reported difficulty passing the coil through the micro catheter and it moved suddenly and ruptured the aneurysm. The ruptured aneurysm was clotted by the completed deployment of the device. No MDR was submitted until 4/8/10. Complaint #15607, received 2/24/10 involved a reported jumping of a microcatheter manufactured by another firm used with our firm's coil, resulting in a rupture of the aneurysm. That case resulted in the patient's death. Complaint #15607 was reported as an MDR. Although the latter complaint resulted in a death both complaint involved similar alleged malfunction.

OBSERVATION 2

Corrective and preventive action activities have not been documented, including investigations of causes of nonconformities, the verification or validation of corrective actions, and implementation of corrective and preventive actions.

Specifically, Corrective and Preventive Action No (b) (4) 2/2/09 was opened for sharp edges on the inner and outer diameter of the (b) (4) The actions listed include a new specification for the (b) (4) The specification changes the cut on the (b) (4) from a cross cut to an axial cut. It also calls for a (b) (4) check for sharp edges. The CAPA form does not document the verification of this action. In the section on Effectiveness check it was written that the CAPA is no longer valid because the specification is changed. The effectiveness of the action is the release of the new specification and the effectiveness can be found in the results for the (b) (4) check.

Also CAPA No. (b) (4) 11/11/08 was opened for guidewire introducers (b) (4) having a sharp tip. The verification of actions include the proposed action of the supplier (b) (4) concerning the use of the saw used in the manufacture of the cannula. The second action listed is the Micrus decided not to purchase part form this supplier. The effectiveness check comment says that it is not applicable because business with (b) (4) is discontinued. Officials at your firm told me that the part was replaced with a new part produced by another supplier. (b) (4) is

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	Timothy C. Grome, Investigator	04/12/2010

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still on the list of qualified suppliers so the phrase "business with (b) (4) is discontinued" is misleading. The new part was not referenced in the CAPA and the performance of the new part from the new supplier was not recorded for the effectiveness of this CAPA.

Also Nonconforming Material Report # (b) (4) 7/8/09 was opened for (b) (4) coils failing in-process inspection for being below specification. The specification used for the in-process coil was changed because the final step in the manufacture of the device was adding a thread which increased the diameter by (b) (4) The specification for both in-process and finished device was (b) (4) The disposition of the below specification lot was changed to "use as is" by changing the specification for the in-process pre-thread coil to (b) (4) No CAPA was opened to evaluate whether the specification changes made for this size and type of coil applied to other coil types and sizes.

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Observation Annotations

Observation 1: Corrected and verified.

Observation 2: (b) (4)

*** DATES OF INSPECTION:**
04/06/2010(Tue), 04/07/2010(Wed), 04/08/2010(Thu), 04/12/2010(Mon)

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