

Division of General and Restorative, and Neurological
Devices
General Surgery Devices Branch, HFZ-410
(301) 594-2037

Food and Drug Administration
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

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To: Richard Felten, Neil Ogden, The file

From: Michael J. Schlosser, M.D., Medical Officer

Subject: Concentric Medical Retriever Clinical consult - *addendum*

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On 1/28/2004, Concentric Medical provided updated data to FDA for their MERCI trial. This data included 129 patients treated with the Retriever, 30 day follow-up for 121 patients, and completed 90 day follow-up for 106 patients. In Table 2 of the Revised Summary of Clinical Results, the sponsor has provided updated primary endpoint and secondary endpoint results for this expanded population. No substantial changes were seen in the revascularization rate, serious device-related adverse event rate, or the overall major adverse event rate. The analysis of the primary endpoint success and safety data were thus not changed by this updated information.

There were, however, some small changes in the clinical outcome data at 90 days. The percent of patients experiencing a good outcome (modified Rankin scale score of = 2) increased to 28% for all patients in the trial, and to 30% when examining only patients with occlusions in the middle cerebral artery (MCA). When compared to the control group of PROACT II (see table 4-A below), this indicated a slight trend towards improved outcome with the Retriever over the placebo group. The absolute increase (5%) and the number of patients (15 in PROACT II vs. 17 in MERCI) are too small for statistical comparisons or to draw clinical conclusions based on this data.

Modified Table 4, from the Clinical Review memo, to reflect the updated 90 follow-up for the MERCI MCA group.

Table 4-A

	MERCI MCA	PROACT II placebo
Baseline NIHSS median (range)	19 (9-40)	17 (4-28)
mRS < 3 at 90 day follow-up	17/57 (30%)	15/59 (25%)

Michael J. Schlosser, MD
Medical Officer
ODE/DGRND/GSBD