On March 9, 2015, an Establishment Inspection Report (EIR) was issued by the FDA upon the completion of a routine and scheduled medical device inspection at Nemaris, Inc. headquarters.

Summary:

This pre-announced inspection of a registered Class II medical device software manufacturer was conducted pursuant to NYK-DO's 2015 workplan under FACTS Assignment # 11465552; and in accordance to Compliance Program, Inspection of Medical Device Manufacturers, 7382.845 covering PAC's 82845A. The assignment requested a Level I (Abbreviated) medical device inspection be conducted. The previous inspection conducted 0713112013 was classified NAI. The current inspection covered the firm's operation as a medical device software manufacturer of Class II medical device. The QSIT Level II (Abbreviated) inspectional approach was used in conducting the QSR/cGMP inspection covering the following two major subsystems: Corrective and Preventive Action and Production and Process Control. The records reviewed during the current inspection included but are not limited to: device history records, complaint files, corrective actions, and production records. No FDA - 483 was issued and no samples were collected.

Results:

A finding of "No Action Indicated" (NAI) was reported by the FDA Inspector and can be verified by going to the FDA's web site: http://www.accessdata.fda.gov/scripts/inspsearch/

District	Firm Name	City	State	Zip Code	Country / Area	Inspection End Date	Center	Project Area	Classification
NYK	Nemaris Inc	New York	NY	10003	US	03/05/15	CDRH	Compliance: Devices	NAI
NYK	Nemaris Inc	New York	NY	10003	US	07/31/13	CDRH	Compliance: Devices	NAI

No refusal was encountered during the inspection, and there were no reported recalls.