Establishment Inspection Report	FEI:	**2649622**
Medtronic Puerto Rico International dba Medtronic Puerto Rico Operations Co.	EI Start:	10/01/03
Villalba, PR 00766	EI End:	10/10/03

SUMMARY

This pre-announced pre-market/post-market PMA inspection of a critical device manufacturer was conducted as part of SJN-DO's FY-20 04 workplan. It was conducted per CDRH request under FACTS assignments 446563, 389719 and 294119 following the guidance of CP 7383.001 "Me dical Device Premarket and Postmarket Inspections". The three assignments were covered but are reported under only one FACTS assignment number (446563). The assignments included the following post-market PMA's : P 930029/S18 P010015 and P010031 and the pre-market inspection for PMA P030020.

In addition, a level 1 QSIT inspection was conducted following CP7382.845 "Ins pection of Medical Device Manufacturers". The inspection covered Corrective and Preventive Actions, and Production and Process Controls. Coverage of Production and Process Controls focused on assembly operations. This inspection was conducted concurrently with the Neurological wing, reported under FEI: 3003135170.

Previous inspection was conducted July 2001 and was classified NAI. Current inspection revealed no significant deviations for operations conducted at the site. No FDA-483 was issued.

No samples were collected.

ADMINISTRATIVE DATA

Inspected firm:	Medtronic Operations Puerto Rico
Location:	Road #149 Km 56.3 Villalba, Puerto Rico
Phone:	787-847-3500
FAX:	787-847-3545
Mailing address:	Road #149 Km 56.3 P.O. Box 6001 Villalba PR 00766
Dates of inspection:	10/1-10/10/03
Days in the facility:	10/1-3,10/6-10/03
Participants:	Lisa M. Lopez, CSO / Hector Colon, CSO

This report was written by Investigator Lisa M. Lopez. In this report "I " makes reference to Investigator Lopez, "we" indica tes both Hector Colon and Investigator Lopez.

HISTORY

The firm is now part of Medtronic Puerto Rico Operations Company (MPROCO), a controlled foreign corporation formed in October 2001 to oversee all Medtronic plants in Puerto Rico, including this site, Medtronic Neurological Operations in Villalba, PR (formerly Medtronic Europe), Med-Rel in Humacao, PR and the new Medtronic Facility in Juncos, PR. Medtronic, located at Minneapolis MN, is the parent corporation for MPROCO.

INTERSTATE COMMERCE/ JURISDICTION

The firm continues to manufacture leads for pacemakers and defibrillators, and ablation catheters. More than 99% of all products manufactured at this site are shipped outside the Island. Approximately 60% of the products are shipped to the continental USA, while the remaining goes to other countries around the world. Exhibit 1 is a graph provided to depict the product distribution pattern.

RESPONSIBILITY

Responsibility remains basically as last inspection. An organizational chart is included as Exhibit 2. Responsibilities correspond to the position titles. The most responsible individual at this site is German Torres, Plant Manager. Post inspectional correspondence should be directed to him at the address above.

We presented our credentials and issued an FDA-482 to Jorge R. Cabrera Roche, Quality System Manager. He was the most responsible individual for this site at the start of the inspection. Mr. Cabrera's a uthority was evident as all documentation related to processes, validations, SOP's, quality audits, changes, etc. are signed by him. Mr. Cabrera identified German Torres, Plant Manager as the most responsible individual at this facility. However, Mr. Torres was not available at the start of the inspection.

In addition to Mr. Cabrera, we presented our credentials to Norman Ganion, Sr. Principal QA Regulatory/Clinical Auditor with offices at Minneapolis, MN, [redacted] Document Control, Daisy Pagan, CP System. [redacted] Technical Services, [redacted] and [redacted], Coodinators, [redacted], Production [redacted] Alvarado, Human Resources, Angel Torres, Manufacturing Manager.

Mr. Cabrera Roche provided most of the information in this report. In addition to Mr. Cabrera, Mr. Ganion and Mr. Berly Torres accompanied us thorough the inspection.

MANUFACTURING / DESIGN OPERATIONS

The firm manufactures leads for pacemakers and defibrillators. In addition, ablation catheters are manufactured at this location. The leads are assembled, packaged and [redacted] sterilized on-site. Ablation catheters are manufactured and packaged at this location, but they are [redacted] sterilized off-site.

In order to facilitate the pre-market and post-market coverage during the inspection, production and process controls was selected as the second subsystem. The assembly process was selected since it applies to all products manufactured at this facility. Exhibits 3 and 4 are flowcharts for the assembly of the Conductor and Contactor catethers. The following steps have been defined as special process requiring validation: butt joint, welding, crimping, shaft preparation, and packaging. We reviewed the validation protocols and reports for all those processes. Bonding was validated as part of product design. All other assembly steps are 100% verified.

Environmental conditions are monitored and kept at 60-80F and 30-60% humidity. Environmental sampling is conducted weekly to monitor the bioburden. The integrity of air filters is verified annually.

The following equipment is used in the manufacture of catheters: resistance welder, butt joint machine, pouch sealer, and an ultrasonic welder. We reviewed the qualification reports for all these pieces of equipment.

In addition to verifying that all processes that could not be 100% verified were validated and that equipment used was qualified, I reviewed a sample of 35 batch records using row D of the 99% confidence level table. No deviations were observed from this sample.

In addition, I reviewed training records and verified that employees involved in the assembly process were trained to do the tasks assigned.

CAPA

The firm's has t hree CAPA systems covering all CAPA actions. Management is working to have these systems rnerged into one database system. Review of CAPA procedures revealed no deficiencies. In order to challenge the CAPA system, I sampled complaint records and nonconforming material reports using the 99% confidence level table, row D. During review of these records we found a complaint, E514579-1, included as exhibit 5 that was entered in the database three months posterior to the receipt. An MDR was filed for this complaint.

We also found a corrective action plan implemented after findings problems with a curing oven. Review of documentation revealed that this oven was recently moved to a new location. I reviewed the equipment qualification documentation, which seemed to be in order. I asked management if they had investigated to find out why an oven that seemed to work fine during OQ/PQ, had stopped working soon after starting production.

Mr. Cabrera indicated that this OQ/PQ was conducted during a shutdown, when ancillary and supporting systems were not in use. When the same oven was operated concurrently with other equipment, the oven showed a number of problems, including getting out of calibration.

Mr. Cabrera and Mr. Ganion added that this deficiency, not running equipment qualifications under actual conditions of use, was found during an internal audit. Mr. Cabrera showed me the corrective actions instituted to address this problem. Between the actions, the firm had decided to re-qualify the oven. However, I noted no other equipment was identified as scheduled for re-qualification. I encouraged them to conduct a company-wide assessment

Complaints and MDR's are handled by the designated unit at Rice Creek, MN. After initial evaluation, if the designated unit determines that the complaint may be caused by a manufacturing problem, then it is forwarded to the manufacturing site. Otherwise, the investigation is conducted at headquarters. Complaints are also trended by headquarters.

Locally, processes are analyzed to identify trends that may need corrective action.

In addition to complaints and non-conforming material reports, we examined MDR records. MDR's are handled by the firm's he adquarters located at Rice Creek Minnesota. CAPA actions generated if required by headquarters as necessary.

Post-market/Pre-market Coverage

Review of complaints and MDR's related to the PMA's covered during this inspection did not reveal any apparent trend. Coverage of Production and Process Controls focused on the assembly of catheters similar to the catheters covered under PMA P030020. The firm has been manufacturing the catheters for the European market for many years. All processes identified as not 100% verifiable had been validated.

Management indicated that the model 4189, covered by P010031 was withdrawn from the rnarket because it was replaced by model 4193 that is covered under P10015. No significant changes have been made to these products except those already submitted as PMA supplements.

We collected labeling for the following products:

Exhibit #	Model #	Product Description
6	4193	**Attain OTW Steroid diluting, transvenous, unipolar, left ventricular, over the wire, cardiac vein pacing lead**
7	2187	**Attain LV transvenous, unipolar, left ventricular, cardiac vein pacing lead**
8	2188	**Attain CS Transvenous, bipolar, coronary sinus/cardiac vein pacing lead**

Corrections and Removals

All corrections and removals are handled by corporate at Rice Creek, MN. Since the last inspection two recalls have been initiated for products manufactured at this facility. Both recalls were reported to the FDA in August 2002, and have numbers assigned to them: Z-320 and Z-321. These recalls are related to wire fractures in catheters. The problem was addressed by the firm and the recalls have been closed by the agency.+

Tracking

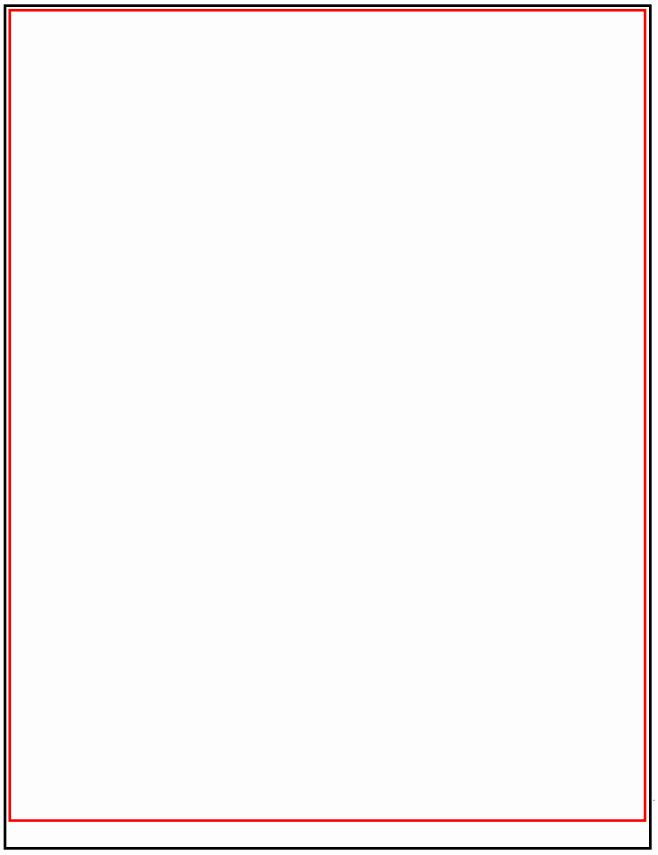
Most devices manufactured at this site are subject to the tracking regulations. Tracking is handled by the Patient Services Department of Medtronic at Minneapolis. I discussed with management how audits are conducted. Audits are conducted to simulate a field action, but only include devices within three years after distribution. I reminded management that the tracking regulations apply throughout the life of the device. I indicated that it would be a good idea to include in audits devices throughout their whole expected range of life.

OBJECTIONABLE CONDITIONS/DISCUSSION WITH MANAGEMENT

The following personnel were present for the closeout interview:

Josue Reyes, IT & Document Management Manager

Olga L. Serrano Rosario, Operation Manager



Jose Munoz Santos, Sr. QA Engineer

Since no significant deficiencies for operations at this location were observed, no FDA-483 was issued. However, during review of MDR's, we foun d one event out of 35 that was entered in the complaint system 4 months after receipt. Complaints and MDR's are h andled by a designated complaint unit located at Rice Creek, MN. I encouraged management to investigate instances where complaints were not entered in a timely fashion such as E514579-1. Management promised to relinquish this information to Rice Creek.

In addition, I recommended expanding tracking audit procedures to include devices after implantation and throughout the life of the device. I also encouraged management to consider if re-qualification of other equipment was necessary for other equipment after internal non-conformancies and internal audits found that equipment was not being qualified under actual conditions of use.

ATTACHMENTS

FDA-482
Copy of Assignments from CDRH : 294119, 389719 and 446563

Lisa M. Lopez, CSO

Hector Colon, CSO

Exhibits