DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

Telephone: 949-608-2900
FAX: 949-608-4415

JUN 16 2011

RA/QA Manager
Mireya Lozano
Life Science Outsourcing, Inc.
830 Challenger St.
Brea, CA 92821

Dear Ms. Lozano:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your premises at Life Science Outsourcing, Inc., 830 Challenger St., Brea, CA on April 13, 2011 by Investigator Jocelyn E. Massey on behalf of the U.S. Food and Drug Administration (FDA). When the agency concludes that an inspection is closed under title 21, Code of Federal Regulations, Section 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects only first party redaction's made by the Agency which protects any confidential information external to your firm. This, however, does not preclude you from requesting any additional information under the *Freedom* of Information Act (FOIA).

If there are any questions about released information, feel free to contact me at (949) 608-2900 or to write to:

U.S. Food and Drug Administration
ATTN: Compliance Branch
19701 Fairchild
Irvine, CA 92612-2506

Sincerely,

Alonza E. Cruse
District Director

Enclosure

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SUMMARY

This was a pre-announced post-market inspection of a medical device contract manufacturer conducted per request from CDRH, OC, Division of Risk Management Operations, FOB under FACTS assignment #1256351. The inspection was performed in accordance with CPs 7383.001 and 7382.845 utilizing the QSIT Level I technique. PACs covered were 82845A and 83001A. Profile codes reported were PRF and MTL.

The previous inspection was performed in February 2009 and classified NAI. That inspection was a pre-market inspection of the subject device of this post-market inspection. The current inspection covered the Production and Process Controls and CAPA subsystems as they pertained to the PMA device. Records reviewed included standard operating procedures, environmental monitoring records, CAPA records, and NCMR records.

No FDA-483 observations were noted and no samples were collected. No refusals were encountered.

ADMINISTRATIVE DATA

On 4/13/11 my credentials were shown and an FDA-482 was issued to Barry Kazemi, President/CEO. Also present was Mayra Lopez, Quality Assurance and Regulatory Affairs Manager.

Inspected firm:	Life Science Outsourcing, Inc.
Location:	830 Challenger St Brea, CA 92821
Phone:	714-672-1090
FAX:	(714)672-1093
Mailing address:	830 Challenger St Brea, CA 92821
Registration:	Current
Dates of inspection:	4/13/2011
Days in the facility:	1
Participants:	Jocelyn E. Massey, Investigator

HISTORY

There have been no changes to the firm's history or activities since the previous inspection. LSO continues to manufacture, sterilize, or package and label medical devices under contract for customers in accordance with each customer's specifications and protocols.

JURISDICTION

The [redacted] Catheter, marketed under PMA [redacted], is a Class III medical device used for the treatment of severe, persistent asthma in adults. The device was developed by [redacted] located in [redacted] also holds the PMA for this device.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Barry Kazemi, President/CEO is the owner and most responsible person who has oversight of all the firm's daily activities.

Mireya Lozano, RA/QA Manager remains responsible for implementing the firm's Quality System including handling complaints and CAPAs, document control and quality assurance activities, regulatory affairs and auditing. She reports to Mr. Kazemi.

An organizational chart is included in exhibit 1. Future correspondence should be addressed to Mrs. Mireya Lozano.

MANUFACTURING/QSIT OPERATIONS

As documented in the previous EIR for this firm of which the inspection covered this device, Life Science Outsourcing manufactures the [redacted] Catheter in accordance with [redacted] specifications and protocols. Design controls and validation activities are handled by [redacted] Design files, validation protocols and reports, and device history records are maintained by [redacted] The raw materials and components are supplied by [redacted] to LSO for final assembly, labeling, and packaging for Gamma radiation. Gamma radiation is performed by [redacted] Corporation located in [redacted] The contract manufacturing agreement between LSO and [redacted] is provided in exhibit 2.

CAPA

Corrective and preventive actions are handled according to procedure, "Corrective and Preventive Action System" rev. C03, DCR #3337. I reviewed the CAPA log for 2010 and 2011 and no CAPAs were opened that involved [redacted] or the subject device. I chose to review CAPA 41-10 which involved replacing the steam valves and revalidating sterilizer #113T. The CAPA was opened due to sporadic "low temperature" alerts during sterilization cycles. No deficiencies were found during review of this CAPA.

Complaints are handled in accordance with procedure, "Customer Complaint System" rev. B11, DCR #3337. I reviewed the complaint log for 2010 and 2011 and no complaints were opened that involved [redacted]

Production and Process Controls/Environmental Controls

The [redacted] catheter is assembled in Room #127. This is a Class 10,000 cleanroom.

Environmental monitoring is performed in accordance with procedure, "Monitoring of Controlled Environments" rev. D08, DCR #3412 (exhibit 3). Particulate testing is conducted annually, air sampling is performed quarterly, and microbial testing is performed when needed or when requested by the firm's customers. CEPA Company performs the particulate testing; and microbial testing services when conducted, are provided by SGS, Lincolnshire, IL. I reviewed particulate monitoring records for calendar year 2010 and no deficiencies were noted. I reviewed microbial monitoring for February 2011 and no deficiencies were noted.

I reviewed and collected a copy of a shop traveler/DHR for the [redacted] Catheter (exhibit 4). Training records are maintained in binders that are organized by manufacturing processes. I reviewed training records for the employees whose job tasks are the following:

[redacted]

[redacted]

No training deficiencies were noted.

I reviewed current calibration records for the ExFo R2000 Radiometer and the HH-26K Digital Thermometer and no deficiencies were found. Calibration is performed by PME Services, Inc., Orange, CA.

Non-conformances are handled according to procedure, "Control of Non-conformances" rev. C04, DCR #3418. No non-conformances related to [redacted] product have been opened in 2011. I chose to review NCR#03-021-11 dated 2/28/11, which involved LSO Oven Chamber # LSO-026T-A. The temperature controller on this chamber read 8°C lower than the actual temperature that was recorded on the chart recorders. An investigation revealed that the chamber's temperature controller had been placed in "calibration mode" and the setting was offset at 8°C from the calibrated setting. The unit was taken out of service, recalibrated, and placed back in service.

MANUFACTURING CODES

The [redacted] catheter is identified in house by a 6-digit lot number that indicates the month, day, and year of manufacture:

021411
02= February
14= 14th day
11= 2011

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No objectionable conditions were noted.

REFUSALS

No refusals were encountered.

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

1. Organization chart
2. Manufacturing agreement
3. SOP "Monitoring of Controlled Environments"
4. [redacted] Catheter shop traveler

ATTACHMENTS

1. Memorandum assignment dated 1/27/11
2. FDA-482 Notice of Inspection dated 4/13/11

Jocelyn E. Massey

Jocelyn E. Massey, Investigator