Department of Health and Human Services

Food and Drug Administration

Pacific Region
Los Angeles District
19701 Fairchild
Irvine, CA 92612-2506
Phone: (949) 608-2900
Fax: (949) 608-4417

October 19, 2016

Barry Kazemi
Chief Executive Officer
Life Science Outsourcing, Inc.
830 Challenger St.
Brea, CA 92821

Dear Mr. Kazemi:

The U.S. Food and Drug Administration (FDA) conducted an inspection at 830 Challenger St., Brea, CA 92821, ending June 30, 2016. Effective April 1, 1997, when the Agency determines an inspection is closed under 21 C.F.R. 20.64 (d)(3), FDA releases a copy of the inspection report to the inspected firm.

You will find a copy of the FDA Establishment Inspection Report attached. FDA may have redacted some information in accordance with the Freedom of Information Act (FOIA) and Title 21, Code of Federal Regulations Part 20. Firms may request a copy of their FDA inspections completed prior to April 1, 1997 through FOIA.

FDA is working to make its regulatory process and activities more transparent to the regulated industry. Part of this effort is releasing a copy of your inspection report or summary to you, or acknowledging that the state provided you a copy of the close of their inspection.

Please contact our office if you have questions.

Sincerely,

CDR Steven E. Porter, Jr.
Los Angeles District Director

Enclosure:
FEI: 3001236549

SP: dd

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SUMMARY

A Premarket Approval (PMA) Postmarket Inspection ([redacted] was conducted in accordance with C.P. 7383.001, Medical Device Premarket Approval and Postmarket Inspection, for PMA [redacted] pertaining to the firm's [redacted] LSO is currently registered with the FDA as a Contract Manufacturer, Contract Sterilizer, and Manufacturer of various Class 2 and Class 3 non-sterile and sterile devices and accessories, including orthopedic implants, cannulae, neurological stereotaxic instruments, administration sets, arthroscopes, and electrical stimulators.

The previous inspection of the firm was conducted 03/19/14 – 03/20/14 was Classified NAI and no FDA 483, Inspectional Observations, was issued to the firm at that time.

This inspection was conducted as a Level I QSIT inspection. The Corrective and Preventive Action (CAPA) and Production & Process Controls subsystems were covered. The quality data sources reviewed under the CAPA subsystem were complaints and CAPA reports. Medical Device

Reporting and recalls are the responsibility of LSO's customers; therefore, these CAPA Satellite Program Areas were briefly discussed. The processes reviewed were: cleaning, packaging, and inspection of the [redacted] and environmental monitoring of the cleanrooms. I also reviewed all changes made to the manufacturing specifications of the [redacted] since PMA approval.

The following deficiencies were observed:

1. Procedures for corrective and preventive action have not been adequately established.

2. A process whose results cannot be fully verified by subsequent inspection and test has not been validated according to established procedures.

3. Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

4. Procedures to control environmental conditions have not been adequately established.

At the conclusion of the inspection, an FDA 483, Inspectional Observations, was issued to and discussed with Mr. Barry A. Kazemi, President & CEO. Mr. Kazemi agreed with, and promised to correct, all observations, but requested the FDA 483 not be annotated. Mr. Kazemi promised a written response to the FDA within 15 business days.

No refusals were encountered and no samples were collected during this inspection.

ADMINISTRATIVE DATA

Inspected firm:	Life Science Outsourcing, Inc.
Location:	830 Challenger St Brea, CA 92821-2946
Phone:	714-672-1090
FAX:	-(714)672-1093
Mailing address:	830 Challenger St Brea, CA 92821-2946
Dates of inspection:	6/27/2016-6/30/2016
Days in the facility:	4
Participants:	**Janet Pulver, Investigator**

This inspection was preannounced to Ms. Latha (NI) Chelvakumar, Director of QA/RA, on 06/22/16.

On 06/27/16, I displayed my credentials and issued an FDA 482, Notice of Inspection, to Mr. Barry A. Kazemi, President & CEO and highest management official at the firm.

At the conclusion of the inspection, an FDA 483, Inspectional Observations, was issued to and discussed with Mr. Barry A. Kazemi, President & CEO.

HISTORY

Life Science Outsourcing, Inc. (hereafter referred to as "LSO" or "the firm") was established by Mr. Barry A. Kazemi, President and CEO. The firm was incorporated in the state of California in 1997 as a contract manufacturer, and subsequently expanded and began providing packaging validation and moist heat sterilization services in the early 2000s, and ethylene oxide sterilization in 2014.

LSO manufactures medical devices in accordance with their customer's specifications and procedures. Design controls are the responsibility of the customers, but design files, validation protocols and reports, and device history records can be maintained at either LSO or their customer's site as outlined in each contract agreement. Raw materials and components are typically supplied by each customer to LSO for final assembly, labeling, and packaging. Sterilization for sterile products is carried out at the contract sterilization facility chosen by their customer, or in-house if the products are sterilized by moist heat or Ethylene Oxide. The firm currently has 107 active customers.

Mr. Kazemi reported one affiliated firm:

MPS Medical Inc.
830 challenger st. suite 200
Brea , CA 92821
[FEI Number:3011183328]

Mr. Kazemi provided a copy of the firm's organizational chart (**Exhibit #1**) and reported the following key management changes that have occurred since the last inspection in 2014:

- Latha (NMI) Chelvakumar was hired on January 4, 2016 as Director of QA/RA, to replace Mr. Paul Trujillo who left the firm in November 2015
- Mireya (NMI) Lozano, formerly the RA/QA Manager, was promoted to Director of Operations and Incubator Services

There are currently a total of 92 employees at the firm (82 full time employees and 10 temporary employees). Office hours are 7:00 a.m. to 5:00 p.m., Monday through Friday; production hours are 7:00 a.m. to 3:30 p.m., Monday through Friday.