DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	6/18/2018-6/22/2018* FEI NUMBER 3007666314

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Timothy P. Herbert, President & CEO	
FIRM NAME Inspire Medical Systems Inc.	STREET ADDRESS 9700 63rd Ave N Ste 200
CITY, STATE, ZIP CODE, COUNTRY Maple Grove, MN 55369-6202	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically,

The following MDRs were submitted late (more than 30 days after the aware date):

Complaint (PRF) #	Aware Date	MDR Date	Filing Days
1748	07-MAR-2018	01-MAY-2018	55
1745	13-MAR-2018	01-MAY-2018	49
1737	08-MAR-2018	01-MAY-2018	53
1670	08-AUG-2017	09-MAR-2018	213
1611	10-JAN-2018	26-FEB-2018	47
1544	05-DEC-2017	08-FEB-2018	65
1516	20-NOV-2017	10-JAN-2018	51
1447	24-OCT-2017	22-DEC-2017	59
1170	10-MAR-2017	12-MAY-2017	63
745	03-AUG-2016	26-OCT-2016	84

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Susan M Matthias, Investigator	X Susan M Matthias Investigator Signed By: Susan M. Matthias - S Date Signed: 06-22-2018 10:08:03	6/22/2018

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OBSERVATION 2

Corrective and preventive action activities and/or results have not been adequately documented.

Specifically,

Supplier CAPAs do not have corrective actions documented, and do not have responses documented within 30 days as required by your procedure. Examples include:

- SR0009 regarding short shots on "insulator cup" component part of the IPG which holds the battery and circuit board, initiated 07-FEB-2017 with response due 14-APR-2017, did not document the corrective action plan or implementation evidence until during this inspection on 18-JUN-2018.
- SR0011 regarding missing weld blocks on circuit boards, initiated "August 2017" with initial response due "September 2017", did not document the corrective action plan or implementation evidence until during this inspection on 19-JUN-2018, and back-dated the sections with 20-MAR-2018.
- SR0013 regarding labeling error on finished devices (inaccurate serial number), initiated 14-NOV-2017 with response due 14-DEC-2017, did not document the Corrective Action implementation evidence, the verification or closure.

***DATES OF INSPECTION**

6/18/2018(Mon), 6/19/2018(Tue), 6/20/2018(Wed), 6/22/2018(Fri)

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Maple Grove, MN 55369-6202	Manufacturer

Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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	Susan M Matthias, Investigator X Susan M Matthias Investigator Signed By: Susan M. Matthias -S Date Signed: 06-22-2018 10:08:03	6/22/2018

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."