

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
DISTRICT ADDRESS AND PHONE NUMBER 250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612) 334-4100 Fax: (612) 334-4134		DATE(S) OF INSPECTION 12/15/2025-12/19/2025 FEI NUMBER 3030499299					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jason P. Kelly, Chief Operations & Quality Officer							
FIRM NAME INSPIRE MEDICAL SYSTEMS INC		STREET ADDRESS 6105 Golden Hills Dr Suite 100					
CITY, STATE, ZIP CODE, COUNTRY Golden Valley, MN 55416-1023		TYPE ESTABLISHMENT INSPECTED Specification Developer					
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. <i>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.</i>							
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established. Specifically, Your procedure "Product Report Review, Investigation and Processing," QSWI-07-00007, Version 11, Effective March July 24, 2025, and "U.S MDR Reporting," QSWI-09-00001, Version 4, Effective August 19, 2024, are not adequately implemented. MDR rationale for not reporting deaths lacks documentation Further, complaint investigations regarding patient deaths are not adequate. Additionally, complaints are not processed in a uniform and timely manner. 1. Your procedure "U.S MDR Reporting," QSWI-09-00001, Version 4, Dated August 19, 2024, Section 7.7 .notes "If Inspire has information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur, an MDR is not required. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. MDR event files must contain the information that the qualified person used to determine whether or not a device-							
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related event was reportable.” However, MDR rationale for not reporting deaths lacks this documentation. a. PRF 37033 was opened on (b) (6), (b) (7)(C), due to a patient passing away for unknown causes. Your firm initially decided to not report the death because “Patient death unrelated to Inspire. No device malfunction reported.” There is no additional documentation or evidence supporting this conclusion. After an investigation and root-cause was completed, a second MDR evaluation was conducted and the rationale to not report was “Patient death unrelated to Inspire. No device malfunction reported.” However, there is no additional documentation or evidence supporting this conclusion. b. PRF 40333 was opened on (b) (6), (b) (7)(C), due to a patient death with an unknown cause of death. Your firm initially decided to not report the death because “Patient death unrelated to Inspire. No device malfunction reported.” There is no additional documentation or evidence supporting this conclusion. After an investigation and root-cause was completed, a second MDR evaluation was conducted and the rationale to not report was “Patient death unrelated to Inspire. No device malfunction reported.” However, there is no additional documentation or evidence supporting this conclusion. c. PRF 39125 was opened on (b) (6), (b) (7)(C), due a patient passing away unexpectedly and it is unknown if the death is related to Inspire. Your firm initially decided to not report the death because “Patient death has not been attributed to Inspire by a physician. Reportability will be reassessed following root cause analysis.” After an investigation and root-cause was completed, a second MDR evaluation was conducted and the rationale to not report was “Patient death unrelated to Inspire. No device malfunction reported.” However, there is no additional documentation or evidence supporting this conclusion. d. PRF 41784 was open (b) (6), (b) (7)(C), due to a reported patient death with no cause of death determined, Your firm initially decided to not report the death because “Patient death has					
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not been attributed to Inspire by a physician. Reportability will be reassessed following root cause analysis.” There is no additional documentation or evidence supporting this conclusion. This complaint is still in the investigation and root-cause phase and awaiting the device to be returned. 2.Complaint investigations and root cause regarding patient deaths are not adequate. a. Root Cause and Conclusion in PRF 37033 states “According to the patient’s son, an autopsy was not performed. Medical examiner said that it was likely death of natural causes. Based on the available information, root cause of the patient’s death was concluded as natural causes, unrelated to Inspire. There was no allegation or evidence of a product nonconformance.” There is no additional documentation or evidence supporting this conclusion. b.Root Cause and Conclusion in PRF 40333 states “The provided reported that the patient died on (b) (6), (b) (7)(C)His cause of death is unknown. The physician does not attribute the patient’s death to Inspire. There was no allegation or evidence of a product conformance. Root cause concluded as most likely the patient’s non-Inspire related health condition.” There is no additional documentation or evidence supporting this conclusion. c.Root Cause and Conclusion in PRF 39125 states “The FCR reported the patient did not die from anything related to Inspire. Root cause of the patient’s death was concluded as the patient’s non-Inspire related health condition. There was no allegation or evidence of a product nonconformance.” There is no additional documentation or evidence supporting this conclusion. 3.Complaints are not processed in a uniform and timely manner. a. PRF 38460 opened 06/25/2024 with an Initial Harm Severity of (b) (4)[Product report			
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investigation shows no hazard occurred. Can be related to intra-operative testing, or out-of-box failures if implant of the device did not take place] has a Root Cause and Conclusion due date of 10/16/2024. Last edit date of the record was 09/18/2024. Complaint is still open. b.PR# 40661 opened 08/30/2024 with a Post Harm Severity of (b) (4) [An infection related to the Inspire System Implant or procedure that requires surgical intervention (explant/revision) to resolve] has a Record Closure due date of 02/26/2025 At the time of the review of this complaint, all parts of the complaint record have been completed except for Record Closure. The complaint was closed during the inspection. c.PR# 41498 opened 09/25/2024 with a Post Harm Severity of (b) (4) [Reduced therapy effectivity (including no output) that can be resolved without clinician intervention] has Record Closure due date of 03/24/2025. At the time of the review of this complaint, all parts of the complaint record have been completed except for Record Closure. The complaint was closed during the inspection. d.PR# 42522 opened 10/24/2024 with an Initial Harm Severity of (b) (4) [Symptoms that cannot be resolved by adjusting the patient remote...A painful non-therapeutic shock or jolting stimulation pulse (not from external electrical source) requiring clinical intervention (adjustment of therapy setting) to continue with Inspire therapy]. The complaint was closed and then re-opened 06/05/2025. The Root Cause and Conclusion section's due date is 07/05/2025. Complaint is still open. e.PR# 46904 opened 02/19/2025 with an Initial Harm Severity of (b) (4) [Reduced therapy effectively (including no output) that can be resolved with clinician intervention such as changing the IPG setting or changing settings only accessible by the clinician] has a Root Cause and Conclusion due date of 09/24/2025. The last edit date of the record was 08/25/2025. Complaint is still open.							
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f.PRF 47889 opened 03/14/2025 with an Initial Harm Severity of (b) (4) [Discomfort from the hypoglossal nerve or other nerves that does not require clinical intervention to resolve] has a Root Cause and Conclusion due date of 11/05/2025. The last edit date was on 07/21/2025 with update about the patient progress. Complaint is still open.

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Annotations to Observations

Observation 1:

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Alicia U Jacobo, Investigator

X
Alicia U Jacobo
Investigator
Signed By: Alicia U Jacobo -S
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12/19/2025

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."