DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	3/4/2026-3/12/2026* FEI NUMBER 3009134706

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dustin A. Heldman, PhD, President and COO

FIRM NAME	STREET ADDRESS
Great Lakes Neurotechnologies Inc	6100 Rockside Woods Blvd N Ste 415
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Independence, OH 44131-2366	medical device 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

Records of risk management activities in product realization were not adequately maintained.

Specifically, your "Risk Assessment for Kinesia Family of products" (dated 4/2023) is inadequately maintained. For example:

(a) Your Risk Assessment does not include any documented risk control measures, as required by sections 6.1 and 7.3 of procedure #7.2.5, "Risk Management" (dated 2/18/2022).

(b) Your Risk Assessment lacks clear definitions and documentation of mitigation activities. Additionally, your "Risk Management" procedure does not define triggers that indicate when mitigation is required. There are (b) (4) Risk IDs listed on your Risk Assessment, 80 Risk IDs (b) (4) include the statement "*No further mitigation determined*." For example, Risk ID #4.18 ("*Sensor is swallowed*") received the highest risk rating of (b) (4) but has no documented mitigation.

(c) The procedure states that a "*Benefit-Risk ratio will be assessed*" but does not specify when this assessment is required or how it will be utilized.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Laureen M Geniusz, Investigator	X Laureen M Geniusz Investigator Signed By: Laureen M. Geniusz -S Date Signed: 03-12-2026 10:56:35	3/12/2026

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*DATES OF INSPECTION

3/04/2026(Wed), 3/09/2026(Mon), 3/10/2026(Tue), 3/11/2026(Wed), 3/12/2026(Thu)

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Annotations to Observations

Observation 1: Promised to correct

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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."