DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	8/25/2025-8/28/2025
	FEI NUMBER 3002743211

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Robert L McMillan, Vice President

FIRM NAME	STREET ADDRESS
Northern Digital Inc.	103 Randall Drive
CITY, STATE, ZIP CODE, COUNTRY Waterloo, N2V 1C5	TYPE ESTABLISHMENT INSPECTED 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

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

Specifically, your firm's procedure Medical Device Complaint Handling, QP-850-302, Rev 012, September 20, 2024, is not adequately established. Your firm is a Manufacturer of Class II Reflective Marker Spheres, 510(k)s K100038 and K033621, exported and intended for the US market, and your firm is not able to provide evidence of investigating all complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications between August 1, 2024, and August 28, 2025, for complaints received for the US market, including to ensure your firm reviews and evaluates all complaints in a uniform and timely manner to determine whether an investigation is necessary and are evaluated to determine whether the complaint represents an event, which is required to be reported to the US FDA under 21 CFR Part 803 - Medical Device Reporting (MDR).

OBSERVATION 2

Written MDR procedures have not been implemented.

Specifically, your firm's procedure USA Medical Device Reporting (MDR), QP-821-302, Rev 006,

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	Felix J Marrero, Investigator - Dedicated Device Cadre X Felix J Marrero Investigator - Dedicated Device Cadre Signed By: Felix J. Marrero -S Date Signed: 08-28-2025 17:21:25	8/28/2025

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February 6, 2023, is not adequately established. Your firm is a Manufacturer of Class II Reflective Marker Spheres, 510(k)s K100038 and K033621, exported and intended for the US market, and your firm is not able to provide evidence of ensuring your firm reviews and evaluates all complaints in a uniform and timely manner to determine whether an investigation is necessary and are evaluated to determine whether the complaint represents an event, which is required to be reported to the US FDA under 21 CFR Part 803 - Medical Device Reporting (MDR), between August 1, 2024, and August 28, 2025, for complaints received for the US market.

OBSERVATION 3

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically, your firm's procedure Supplier Control Process, QP-741-201, Rev 018, May 8, 2024, is not adequately established, including:

1. Your firm has no evidence of selecting your sole Contract Manufacturer and three (3) Ethylene Oxide (EtO) Contract Sterilizers for your line of Class II Reflective Marker Spheres, 510(k)s K100038 and K033621, exported and intended for the US market, to ensure these suppliers were selected on the basis of their ability to meet specified requirements, including quality requirements.

2. Your firm has no evidence of established and maintained records of your sole Contract Manufacturer and three (3) Ethylene Oxide (EtO) Contract Sterilizers, as accepted suppliers, and they are not listed on your current Approved Supplier List.

3. Your firm has not established an agreement with your three (3) Ethylene Oxide (EtO) Contract Sterilizers for your line of Class II Reflective Marker Spheres, 510(k)s K100038 and K033621, exported and intended for the US market, to ensure that your firm is notified of changes to the services

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provided, including the EtO sterilization processes and parameters, so that your firm can determine if the changes may affect the quality and safety of your finished medical devices exported and intended for the US market.

OBSERVATION 4

Personnel do not have the necessary background, training and experience to perform their jobs.

Specifically, throughout the inspection, key members of your firm who participated and provided relevant information were not familiar with US FDA regulations and requirements for Manufacturers exporting medical devices intended for the US market, including:

a) 21 CFR Part 803 - Medical Device Reporting
b) 21 CFR Part 807 - Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
c) 21 CFR Part 820 - Quality System Regulation

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: 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."