DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	9/26/2019-9/30/2019* FEI NUMBER 1000517638

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

David (NMI) Anderson, Vice President/General Manager, Enabling Technologies

FIRM NAME	STREET ADDRESS
Medtronic Navigation, Inc.	826 Coal Creek Cir
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Louisville, CO 80027-9710	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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A previously certified laser product which has been modified, which modification affects any aspects of the product's performance or intended function(s), has not been recertified

Specifically, your firm's Visualase™ MRI-Guided Laser Ablation System has a Visualase™ software component that electronically controls a certified laser component produced by a contract manufacturer. The Visualase™ System software allows the user to attenuate the laser beam signal and there are two (2) interlocks that turn off the laser for added patient safety when MRI data indicates that either a high or low temperature threshold was exceeded. However, your firm failed to recertify the modified laser component by filing a Product Report and subsequent Annual Reports with FDA, as required under 21 CFR 1040.10(i).

*DATES OF INSPECTION

9/26/2019(Thu), 9/30/2019(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew M Vernon, Investigator	X Matthew M Vernon Investigator Signed By: 2001860154 Date Signed: 09-30-2019 13:18:54	9/30/2019

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew M Vernon, Investigator	Matthew M Vernon Investigator Signed By: 2001860154 Date Signed: 09-30-2019 13:18:54 X	9/30/2019

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."