UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA
Civil No. 15 - 2168

UNITED STATES OF AMERICA, Plaintiff v. MEDTRONIC INC., a corporation, and S. OMAR ISHRAK and THOMAS M. TEFFT, individuals, Defendants.	COMPLAINT FOR PERMANENT INJUNCTION

INTRODUCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin Medtronic Inc. (“Medtronic”), a corporation, and S. Omar Ishrak, and Thomas M. Tefft, individuals (hereinafter, collectively, “Defendants”) from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of devices, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, and

installation are not in conformity with current good manufacturing practice requirements prescribed at 21 C.F.R. Part 820;

B. 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. § 351(h), as described in paragraph A above, while such devices are held for sale after shipment in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Medtronic is incorporated under the laws of Minnesota. Medtronic Neuromodulation ("Medtronic Neuro"), a business unit of Medtronic, manufactures medical devices, including but not limited to, SynchroMed II implantable infusion pumps. The headquarters of Medtronic Neuro is located at 7000 Central Ave. NE, Minneapolis, MN 55432, and its manufacturing facility is located at 53rd Avenue, NE, Columbia Heights, MN 55421.

5. S. Omar Ishrak is Medtronic's Chairman and CEO. He is the most responsible person at the firm, and oversees the firm's product development, product management, and international relations and sales. He performs his duties at 710 Medtronic Parkway, Minneapolis, MN 55432.

6. Thomas M. Tefft is the Senior Vice President of Medtronic, and the President of Medtronic Neuro. He is the most responsible person at Medtronic Neuro,

and oversees the business unit's product development, research, regulatory compliance and marketing. He performs his duties at 7000 Central Ave. NE, Minneapolis, MN 55432.

7. Defendants have been, and are now, manufacturing and distributing in interstate commerce various articles of devices, as defined by 21 U.S.C. § 321(h), including, but not limited to, SynchroMed II implantable infusion pumps, the subject of this injunction.

8. Defendants' products are devices, within the meaning of 21 U.S.C. § 321(h), in that they are intended to affect the structure or any function of the body of man.

LEGAL STANDARDS

9. A device must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure its safety and effectiveness. 21 U.S.C. § 360j(f). The statutory good manufacturing practice requirement is set out in the quality system ("QS") regulation for devices, 21 C.F.R. Part 820. A device that has been manufactured, packed, stored, or installed in violation of this requirement is deemed to be adulterated. 21 U.S.C. § 351(h).

10. The introduction or delivery for introduction into interstate commerce of an adulterated article of device is a violation of the Act, 21 U.S.C. § 331(a).

11. The adulteration of a device while it is held for sale after shipment in interstate commerce constitutes a violation of the Act, 21 U.S.C. § 331(k).

APRIL 2013 INSPECTION

12. FDA inspected Medtronic Neuro's manufacturing facility on February 14 – April 3, 2013 ("April 2013 inspection"). During the April 2013 inspection, the FDA investigators documented numerous violations of the QS regulation at Medtronic Neuro. Many of these violations related directly to the manufacture of the SynchroMed II implantable infusion pump. FDA investigators observed the following violations of the QS regulation set forth in 21 C.F.R. Part 820:

A. Defendants fail to establish and maintain adequate design validation procedures to ensure that devices conform to defined user needs and intended uses, to complete proper risk analysis, and to document the results of the validation, in violation of 21 C.F.R. § 820.30(g);

B. Defendants fail to establish and maintain adequate procedures to include requirements for identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, in violation of 21 C.F.R. § 820.100(a)(3);

C. Defendants fail to establish and maintain adequate procedures to include requirements for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, in violation of 21 C.F.R. § 820.100(a)(4);

D. Defendants fail to establish and maintain procedures for implementing corrective and preventive action, in violation of 21 C.F.R. § 820.100(a);

E. Defendants fail to establish and maintain procedures for verifying the device design, in violation of 21 C.F.R. § 820.30(f);

F. Defendants fail to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, in violation of 21 C.F.R. § 820.30(i); and

G. Defendants fail to establish and maintain procedures to control product that does not conform to specified requirements, in violation of 21 C.F.R. § 820.90(a).

PRIOR INSPECTIONS

13. FDA inspected Medtronic Neuro's facilities previously in May 2012, January 2011, January 2007, and June 2006. At these inspections, FDA repeatedly observed and documented violations of the QS regulations similar to those cited above during the April 2013 inspection, including, but not limited to, violations involving: design controls (21 C.F.R. § 820.30) and corrective and preventive action (21 C.F.R. § 820.100).

14. At the conclusion of each of the prior inspections, the FDA investigators issued a Form FDA 483 detailing Defendants' numerous violations of the Act to Defendants, and discussed the documented observations with them. Defendants promised corrections at the conclusion of each inspection.

PRIOR NOTICE OF VIOLATIONS

15. Defendants are well aware that their practices violate the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act.

16. FDA issued a Warning Letter dated July 17, 2012 to Defendants, following the May 2012 inspection of the Medtronic Neuro facility. The letter discussed the QS violations involving corrective and preventive actions and complaint handling (21 C.F.R. § 820.198) observed at the inspection. The letter also warned Defendants that further enforcement actions, including injunction, could occur if they did not correct the violations.

17. Defendants also received Warning Letters, dated July 3, 2007 and August 29, 2006, following the January 2007 and June 2006 inspections. These letters also addressed the numerous QS violations, including but not limited to design controls and corrective and preventive action, observed during the inspections and warned of further enforcement actions if corrections were not made.

18. Representatives of Medtronic also attended a meeting with FDA’s Center for Devices and Radiological Health and Minneapolis District Office on January 31, 2013. At this meeting, Defendants stated that they were aware of the violations at their facilities and were taking steps to correct them.

19. At the conclusion of each of FDA's inspections of the firm, the FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act

to a responsible individual at the firm and discussed the documented observations with the recipient.

20. Defendants made promises to correct their violations in written responses to the April 2013 inspection, dated April 24, and several follow-up responses, detailing how and when the corrections promised in the April 24 letter had been made. None of these responses contained adequate evidence that Defendants have corrected their deviations.

21. Based on Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k).

WHEREFORE, Plaintiff prays:

I. That Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, any article of device that is adulterated within the meaning of 21 U.S.C. § 351(h); or

B. violating 21 U.S.C. § 331(k), by causing any article of device to become adulterated within the meaning of 21 U.S.C. § 351(h) while such devices are held for sale after shipment in interstate commerce.

II. That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly and indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) SynchroMed II implantable infusion pumps at or from its Medtronic Neuro facilities, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute the SynchroMed II implantable infusion pumps are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA; and

III. That the Court authorize FDA, pursuant to this injunction, to inspect Defendants' Medtronic Neuro facility to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

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JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
United States of America

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Chad A. Blumenfield, 300 S. Fourth Street, Minneapolis, MN 55415

DEFENDANTS
Medtronic Inc., S. Omar Ishrak, and Thomas A. Tefft

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
21 USC § 332(a)

Brief description of cause:
This case seeks a permanent injunction for violations of the Federal Food Drug and Cosmetic Act and 21 CFR Part 820.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE _____ DOCKET NUMBER _____

DATE
04/27/2015

SIGNATURE OF ATTORNEY OF RECORD
s/ Chad A. Blumenfield

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**.
Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.