UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN MEDICAL PROGRAMMERS WITH PRINTED CIRCUIT BOARDS, COMPONENTS THEREOF, AND PRODUCTS AND SYSTEMS FOR USE WITH THE SAME**	**Inv. No. 337-TA-1396**

NOTICE OF INSTITUTION OF INVESTIGATION

Institution of investigation pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission

ACTION: Notice

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on February 28, 2024, under section 337 of the Tariff Act of 1930, as amended, on behalf of Medtronic, Inc., Medtronic Logistics, LLC, and Medtronic USA, Inc., of Minneapolis, Minnesota, and Medtronic Puerto Rico Operations Co. of Juncos, Puerto Rico. A supplement was filed on March 1, 2024. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain medical programmers with printed circuit boards, components thereof, and products and systems for use with the same by reason of the infringement of certain claims of U.S. Patent No. 8,712,540 ("the '540 patent") and U.S. Patent No. 9,174,059 ("the '059 patent"). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at https://www.usitc.gov.

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

SUPPLEMENTARY INFORMATION:

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10 (2023).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on March 29, 2024, ORDERED THAT –

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1-5, 7, 11, 12, 14, 15, 17, 18, 20, 39, and 40 of the '540 patent and claims 1-5, 7, 11, 12, 14, 15, 17, 18, and 20 of the '059 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "sacral neuromodulation systems to control neurostimulators surgically implanted into a human patient, incorporating medical programmers and printed circuit boards used in same";

(3) Pursuant to Commission Rule 210.50(b)(1), 19 C.F.R. 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432

Medtronic Logistics, LLC
710 Medtronic Parkway
Minneapolis, MN 55432

Medtronic USA, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432

Medtronic Puerto Rico Operations Co.
Ceiba Norte Industrial Park
50 Road 31, Km. 24.4
Juncos, Puerto Rico 00777

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served:

Axonics, Inc.
26 Technology Drive
Irvine, CA 92618

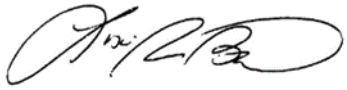
(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Suite 401, Washington, D.C. 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.13. Pursuant to 19 C.F.R. 201.16(e) and 210.13(a), as amended in 85 Fed. Reg. 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: March 29, 2024

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN MEDICAL PROGRAMMERS WITH PRINTED CIRCUIT BOARDS, COMPONENTS THEREOF, AND PRODUCTS AND SYSTEMS FOR USE WITH THE SAME**	**Inv. No. 337-TA-1396**

DESIGNATION OF OUII ATTORNEY FOR SERVICE OF PROCESS

The Office of Unfair Import Investigations ("OUII") hereby designates Claire Comfort, Esq., (202) 205-2160, claire.comfort@usitc.gov as OUII's lead attorney for service of process. It is requested that all documents served by the Commission or filed by the parties in the above- referenced investigation be served upon this attorney

Respectfully submitted,

Margaret Macdonald, Director

OFFICE OF UNFAIR IMPORT INVESTIGATIONS
U.S. International Trade Commission
500 E Street, S.W., Suite 401
Washington, D.C. 20436
(202) 205-2560

March 29, 2024

CERTAIN MEDICAL PROGRAMMERS WITH PRINTED CIRCUIT BOARDS, COMPONENTS THEREOF, AND PRODUCTS AND SYSTEMS FOR USE WITH THE SAME **Inv. No. 337-TA-1396**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INSTITUTION OF INVESTIGATION** has been served via EDIS upon the Commission Investigative Attorney, **Claire Comfort**, **Esq.** and the following parties as indicated, on **March 29, 2024**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

Complainants:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

Medtronic Logistics, LLC
710 Medtronic Parkway
Minneapolis, MN 55432

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

Medtronic USA, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

Medtronic Puerto Rico Operations Co.
Ceiba Norte Industrial Park
50 Road 31, Km. 24.4
Juncos, Puerto Rico 00777

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

On Behalf of Complainants:

Robert T. Vlasis III, Esq.
WINSTON & STRAWN LLP
1901 L Street, NW
Washington, D.C. 20036
Email: RVlasis@winston.com

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

Respondent:

Axonics, Inc.
26 Technology Drive
Irvine, CA 92618

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Service to Be Completed by Complainants

Government Agencies:

Lynda Marshall
International Section, Antitrust Division
U.S. Department of Justice
450 5th Street NW, Room 11000
Washington, DC 20530

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

Dax Terrill, Chief
Exclusion Order Enforcement Branch
U.S. Customs and Border Protection
Regulations and Rulings
90 K Street NE – 10th Floor
Washington, DC 20229

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

Andrew Heimert
International Antitrust, Office of International Affairs
Federal Trade Commission
600 Pennsylvania Avenue, Room 498
Washington, DC 20580

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

Summer E. Young, PH.D., J.D.
HHS Office of the General Counsel, NIH Branch
National Institutes of Health
31 Center Drive
Bldg. 31, Room 2B-50
Bethesda, MD 20892

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Medtronic, Inc
710 Medtronic Parkway
Minneapolis, MN 55432

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Sir/Madam:

This letter is to advise you that the U.S. International Trade Commission has instituted an investigation pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Commission's notice of investigation is enclosed. Also enclosed is the Section 337 Mediation Program brochure. After reviewing the brochure, please sign and return the enclosed certification of receipt.

Sincerely,

Lisa R. Barton
Secretary

Enclosures:
1. Notice of Investigation
2. Publication Regarding the Section 337 Mediation Program
3. Certification of Receipt of Mediation Materials

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Medtronic Logistics, LLC
710 Medtronic Parkway
Minneapolis, MN 55432

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Sir/Madam:

This letter is to advise you that the U.S. International Trade Commission has instituted an investigation pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Commission's notice of investigation is enclosed. Also enclosed is the Section 337 Mediation Program brochure. After reviewing the brochure, please sign and return the enclosed certification of receipt.

Sincerely,

Lisa R. Barton
Secretary

Enclosures:
1. Notice of Investigation
2. Publication Regarding the Section 337 Mediation Program
3. Certification of Receipt of Mediation Materials

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Medtronic USA, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Sir/Madam:

This letter is to advise you that the U.S. International Trade Commission has instituted an investigation pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Commission's notice of investigation is enclosed. Also enclosed is the Section 337 Mediation Program brochure. After reviewing the brochure, please sign and return the enclosed certification of receipt.

Sincerely,

Lisa R. Barton
Secretary

Enclosures:
1. Notice of Investigation
2. Publication Regarding the Section 337 Mediation Program
3. Certification of Receipt of Mediation Materials

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Medtronic Puerto Rico Operations Co.
Ceiba Norte Industrial Park
50 Road 31, Km. 24.4
Juncos, Puerto Rico 00777

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Sir/Madam:

This letter is to advise you that the U.S. International Trade Commission has instituted an investigation pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Commission's notice of investigation is enclosed. Also enclosed is the Section 337 Mediation Program brochure. After reviewing the brochure, please sign and return the enclosed certification of receipt.

Sincerely,

Lisa R. Barton
Secretary

Enclosures:
1. Notice of Investigation
2. Publication Regarding the Section 337 Mediation Program
3. Certification of Receipt of Mediation Materials

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Robert T. Vlasis III
Winston & Strawn LLP
1901 L Street, NW
Washington, DC 20036

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Robert T. Vlasis III:

This letter is to advise you that the U.S. International Trade Commission has instituted an investigation pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Commission's notice of investigation is enclosed. Also enclosed is the Section 337 Mediation Program brochure. After reviewing the brochure, please sign and return the enclosed certification of receipt.

Sincerely,

Lisa R. Barton
Secretary

Enclosures:
1. Notice of Investigation
2. Publication Regarding the Section 337 Mediation Program
3. Certification of Receipt of Mediation Materials

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Axonics, Inc.
26 Technology Drive
Irvine, CA 92618

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Sir/Madam:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). **Axonics, Inc.** is a named respondent in this investigation.

We are hereby serving you with a copy of the Complaint and the Notice of Investigation issued in this matter. Enclosed is a copy of the Code of Federal Regulations. Also enclosed is a the Section 337 Mediation Program brochure. After reviewing this brochure, please sign and return the enclosed certification of receipt.

Please note that the Notice requires a response to the allegations in the Complaint and the response must be received not later than twenty (20) days after the date of service of the Complaint. Failure to file a response may result in inferences being drawn against your interests.

Sincerely,

Lisa R. Barton
Secretary

`

Enclosures:

1. Complaint
2. Notice of Investigation
3. Code of Federal Regulation
4. Publication Regarding the Section 337 Mediation Program
5. Certification of Receipt of Mediation Materials

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Lynda Marshall
International Section
Antitrust Division
U.S. Department of Justice
450 5th Street NW, Room 11000
Washington, DC 20530

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Lynda Marshall:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

Lisa R. Barton
Secretary

Enclosure:
1. Notice of Investigation

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Dax Terrill, Chief
Exclusion Order Enforcement Branch
U.S. Customs and Border Protection
Regulations and Rulings
90 K Street NE, 10th Floor
Washington, DC 20229-1177

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Dax Terrill:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

Lisa R. Barton
Secretary

Enclosure:
1. Notice of Investigation

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Andrew Heimert
Office of International Affairs
Federal Trade Commission
600 Pennsylvania Avenue, Room 498
Washington, DC 20580

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Andrew Heimert:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

Lisa R. Barton
Secretary

Enclosure:
1. Notice of Investigation

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

March 29, 2024

Summer E. Young, Ph.D., J.D.
HHS Office of the General Counsel, NIH Branch
National Institutes of Health
31 Center Drive
Building 31, Room 2B-50
Bethesda, MD 20892

Re: Certain Medical Programmers with Printed Circuit Boards, Components Thereof, and Products and Systems for Use with the Same; Inv. No. 337-TA-1396

Dear Summer Young:

This letter is to advise you that the United States International Trade Commission has instituted an investigation pursuant to Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). A copy of the Notice of Investigation is enclosed. Non-confidential copies of the Complaint and any supplements filed in the investigation will be provided upon request. Requests should be directed to Docket Services at (202) 205-1802.

If you have any questions concerning this investigation, please contact the Commission Investigative Attorney whose name and telephone number appear in the enclosed Notice.

Sincerely,

Lisa R. Barton
Secretary

Enclosure:
1. Notice of Investigation

March 29, 2024