UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS:	Lina M. Khan, Chair Noah Joshua Phillips Rebecca Kelly Slaughter
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COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Medtronic plc, through its subsidiary Respondent Medtronic, Inc., has entered into an agreement to acquire Respondent Intersect ENT, Inc., that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that a proceeding in respect thereof would be in the public interest, hereby issues this complaint, stating its charges as follows.

I. RESPONDENTS

- 1. Respondent Medtronic plc is a public limited company organized, existing, and doing business under and by virtue of the laws of Ireland, with its executive offices and principal place of business located at 20 Lower Hatch Street, Dublin 2, and its United States address for service of process is 710 Medtronic Parkway, Minneapolis, Minnesota 55432.
- 2. Respondent Medtronic, Inc. ("Medtronic"), is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its executive offices and principal place of business located at 710 Medtronic Parkway, Minnesota, Minnesota 55432.

- 3. Respondent Intersect ENT, Inc. ("Intersect"), is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its executive offices and principal place of business located at 1555 Adams Drive, Menlo Park, California 94025.
- 4. Each Respondent, either directly or through its subsidiaries, is, and at all times relevant herein has been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

- 5. Pursuant to an Agreement and Plan of Merger dated as of August 6, 2021, Medtronic proposes to acquire all of the issued and outstanding securities of Intersect ("the Acquisition") for approximately \$1.1 billion.
- 6. The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. NATURE OF THE CASE

7. Medtronic is a large conglomerate medical device manufacturer with an outsized presence in markets for devices used in ear, nose, and throat ("ENT") procedures. Of most relevance here, Medtronic holds a dominant position in the market for ENT navigation systems and is one of only four current competitors in the market for balloon sinus dilation products. The Acquisition would give Medtronic control of the Intersect subsidiary, Fiagon, which is a nascent, innovative competitor to Medtronic for ENT devices, specifically ENT navigation systems and balloon sinus dilation products. But for the Acquisition, Fiagon would be a competitive threat to Medtronic's continued market dominance in ENT navigation systems and would provide physicians and their patients new and innovative treatment options in competition with Medtronic and its other competitors.

IV. THE RELEVANT MARKETS

- 8. The relevant lines of commerce in which to analyze the effects of the Acquisition are the research, development, licensing, manufacturing, marketing, distribution, and sale of (a) balloon sinus dilation products and (b) ENT navigation systems.
- 9. The United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

V. MARKET STRUCTURE

10. The markets for the research, development, licensing, manufacturing, marketing, distribution, and sale of balloon sinus dilation products and ENT navigation systems are both highly concentrated. Beyond Medtronic and Fiagon, there are only two

significant competitors in the market for balloon sinus dilation products—Acclarent, Inc., a subsidiary of Johnson & Johnson; and Stryker Corporation, the now owner of Entellus Medical. Therefore, the Acquisition, if consummated, would reduce the number of independent manufacturers of balloon sinus dilation products from four to three. Fiagon, having just entered the U.S. market in 2021 after securing regulatory approvals, is poised to become an important competitive constraint on these established ENT market leaders, including Medtronic. Medtronic's dominant position in ENT navigation systems is challenged only by Acclarent, Stryker, Brainlab AG, Karl Storz SE & Co. KG, and Fiagon.

VI. BARRIERS TO ENTRY

Entry into each relevant market would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects arising from the Acquisition. *De novo* entry would not take place in a timely manner because product development times, U.S. Food and Drug Aeiopmnitio (m)-2RYon 6 (e)6 (f)5 (f)5 (e)a pluyui-2RYopmnd o(e)4 (dt2R)10 (YE)1 8S

IN WITNESS WHEREOF, the Federal Trade Commission, having caused this Complaint to be signed by the Secretary and its official seal affixed, at Washington, D.C., this