

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

11. 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 Administration approval requirements, and market adoption times are lengthy. A potential entrant into the relevant markets would also need to develop a reputation for consistent quality and service before physicians and health systems would substitute them for currently marketed devices.

VII. EFFECTS OF THE ACQUISITION

12. The effects of the Acquisition, if consummated, may be to substantially lessen competition or to tend to create a monopoly in the relevant markets in violation of 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, by:
 - a. eliminating actual, direct, and future competition between Medtronic and Intersect in the relevant markets; and
 - b. increasing the likelihood in the relevant markets that (1) Medtronic would unilaterally exercise market power, (2) research and development would be reduced, and (3) customers would be forced to pay higher prices.

VIII. VIOLATIONS CHARGED

13. The 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.
14. The Agreement and Plan of Merger entered into by Respondents constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

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 seventh day of May 2022, issues its Complaint against Respondents.

By the Commission.

April J. Tabor
Secretary