

**ANALYSIS OF AGREEMENT CONTAINING  
CONSENT ORDERS TO AID PUBLIC COMMENT**

*In the Matter of Medtronic plc*

*File No. 211-0184, Docket No. C-4763*

**I. Introduction**

The Federal Trade Commission (“Commission”) has accepted for public comment, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Medtronic plc, Medtronic, Inc. (“Medtronic”), and Intersect ENT, Inc. (“Intersect”) (together, “Respondents”). The Consent Agreement is designed to remedy the anticompetitive effects that otherwise would result from Medtronic’s acquisition of Intersect.

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 for approximately \$1.1 billion (the “Acquisition”). The Commission’s Complaint alleges that the Acquisition violated Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and that the Acquisition agreement constitutes a violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the U.S. markets for balloon sinus dilation products and ear, nose, and throat (“ENT”) navigation systems.

The proposed Decision and Order (“Order”) contained in the Consent Agreement requires Respondents to divest to Hemostasis, LLC (“Hemostasis”) the assets and business of Intersect’s subsidiary Fiagon AG Medical Technologies (“Fiagon”). Respondents must complete the transfer no later than 10 days after Medtronic consummates its acquisition of Intersect. The Commission has issued, and Respondents have agreed to comply with, an Order to Maintain Assets that requires Respondents to operate and maintain the divestiture assets in the normal course of business through the date the approved buyer acquires the divested assets.

The Commission has placed the Consent Agreement on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the proposed Order final.

**II. The Relevant Markets and Competitive Effects**

The Commission’s Complaint alleges that the relevant product markets in which to analyze the Acquisition are the research, development, licensing, manufacturing, marketing, distribution, and sale of (a) balloon sinus dilation products and (b) ENT navigation systems. Balloon sinus dilation products are catheter devices used to clear blocked sinuses in patients suffering from chronic rhinosinusitis. ENT navigation systems allow physicians to view and track the location of operating instruments such as balloon sinus dilation products during sinus surgery.

The relevant geographic market in which to analyze the competitive effects of the Acquisition is the United States. Balloon sinus dilation products and ENT navigation systems are medical devices subject to approval by the U.S. Food and Drug Administration before sale in the United States. As such, medical devices not approved for sale in the United States do not provide competitive alternatives for U.S. consumers.

The Acquisition would likely substantially lessen competition in the relevant markets. The U.S. markets for balloon sinus dilation products and ENT navigation systems are both highly concentrated. 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 for its balloon sinus dilation products, is poised to become an important competitive constraint on the established ENT market leaders, including Medtronic. In ENT navigation systems, Medtronic currently holds a dominant position, and the Acquisition would eliminate a nascent competitive threat in Fiagon.

### **III. The Proposed Order and the Order to Maintain Assets**

The proposed Order and the Order to Maintain Assets would remedy the Acquisition's likely anticompetitive effects by requiring Respondents to divest the entirety of the Fiagon business and assets to Hemostasis. Hemostasis is an established participant in the ENT medical device segment and has the expertise, sales infrastructure, and resources to restore the competition that otherwise would have been lost pursuant to the Acquisition. The parties must divest all facilities and equipment, intellectual property, business information, and other assets used with and related to the Fiagon business. Hemostasis also intends to retain Fiagon employees. Because Hemostasis will acquire all assets related to the Fiagon business, and the parties are required to obtain all third-party consents before the divestiture transaction is consummated, Hemostasis will be able to begin manufacturing its own supply of ENT navigation systems and balloon sinus dilation products from day one.

The proposed Order contains additional provisions designed to ensure the effectiveness of the relief. For example, the proposed Order requires the Respondents to assist and cooperate in the defense against any intellectual property litigation related to the Fiagon assets. Respondents are required to provide Hemostasis with transition assistance for up to one year following the divestiture of the assets and must cooperate with and assist Hemostasis to evaluate and offer employment to employees involved in the business and assets subject to divestiture. Respondents have also agreed not to enforce any employee noncompete or confidentiality agreements against Hemostasis relating to employees that interview or accept employment with Hemostasis. The proposed Order and the Order to Maintain Assets further require Medtronic to operate and maintain the divestiture assets in the ordinary course of business, including maintaining the economic viability, marketability, and competitiveness of the Fiagon business until the divestiture transaction takes place.

The Commission will appoint Jeryl Hilleman to act as an independent Monitor to oversee the Respondents' compliance with the requirements of the Order, and to keep the Commission informed about the status of the transfer of the Fiagon business to Hemostasis. The proposed Order requires that the divestiture to Hemostasis be completed no later than 10 days after Medtronic consummates the Acquisition.

In addition to requiring the divestiture of the Fiagon assets and business, the proposed Order requires Respondents to obtain prior approval from the Commission before making certain future acquisitions in the relevant markets for a period of ten years from the date the Order is issued.

The proposed Order also requires Hemostasis to obtain prior approval from the Commission before transferring any of the divested assets to any buyer for the first three years

after Hemostasis acquires the divestiture assets. For the seven years following the initial three-year period, the proposed Order requires Hemostasis to obtain prior approval from the Commission before transferring any of the divested assets to any buyer engaged in the research, development, manufacture, marketing, or sale of any balloon sinus dilation products or ENT navigation systems.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and the Commission does not intend this analysis to constitute an official interpretation of the proposed Order or to modify its terms in any way.