

Medtronic

Endoscopy Operating Unit

Given Imaging Inc.
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USA

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Request For Routine Long-Term Confidentiality for FCC filing of O8PGSB

Given Imaging Inc. hereby requests that the information contained in the enumerated item below pertaining to the above-referenced application be withheld from public disclosure in accordance with Sections 0.457 and 0.459 of the Commission's Rules, 47 C.F.R. following grant of the application.

In support of this request, Given Imaging submits the following:

- **Identification of the specific information for which confidential treatment is sought:**

Schematics
Block diagram
Operational description
User manual*

* User manual confidentiality is requested for 6 months.

The materials set forth in these exhibits, which are segregated from the non- confidential exhibits of the application, are those for which confidentiality is sought.

- **Identification of the Commission proceeding in which the information was submitted or a description of the circumstances giving rise to the submission:**
The proceeding is that involving the application for and certification request for FCC ID O8PGSB
- **Explanation of the degree to which the information is commercial or financial, or contains a trade secret or is privileged:**

This information is embodied in circuit diagrams, detailed explanations, a block diagram and internal photographs of a sealed device designed for ingestion by humans. As such, this material is treated as highly confidential business information and information that could convey trade secrets pertaining to manufacturing and design techniques.

- **Explanation of the degree to which the information concerns a service that is subject to competition:**
The information for which confidentiality is sought is employed in the design and manufacture of medical ingested capsule that are offered on a highly competitive basis. Customers for this equipment have a variety of competing sources of supply from both domestic and foreign suppliers.
- **Explanation of how disclosure of the information could result in substantial competitive harm:**

Disclosure would, in effect, give away the fruits of the labors of Given Imaging's engineering personnel, who have designed the equipment and the manufacturing processes. Disclosure would also offer competitors additional unwarranted insight into the state of product development thereby allowing such competitors an advantage that would not be available to Given Imaging Inc.

- **Identification of any measures taken by the submitting party to prevent unauthorized disclosure:**
The information for which confidential treatment is sought is kept confidential by Given Imaging Inc. and not made available to third parties except pursuant to arrangements designed to prevent public disclosure.
- **Identification of whether the information is available to the public and the extent of any previous disclosure of the information to third parties:**
To the knowledge of those preparing this application, the information has not been disclosed publicly. The protection sought is narrowly drawn and pertains to certain specific implementations of the technology incorporated into the device for which certification is sought.
- **Justification of the period during which the submitting party asserts that material should not be available for public disclosure:**
This material should not be disclosed for at least ten years. While improvements in design are likely to be made during this period, disclosure of the design information would lead to insights into both designs and manufacturing techniques and could have an adverse competitive effect for many years to come. This application contains information that will be used in future applications for similar devices. Disclosure of the information for which confidentiality is sought could jeopardize the protection of such personal private medical information generated for the benefit of patients into whom the device has been used. As such, it is important that information pertaining to the design and operation of this device not be made available to unauthorized persons who might attempt to use knowledge of the design to compromise the applications for which the equipment will be employed.

Respectfully,

DocuSigned by:

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Avishag Metzer
Senior Regulatory Affairs Manager
Given Imaging