

# Medtronic

## Endoscopy Operating Unit

Given Imaging Inc.  
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USA

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### Request For Non-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 for 10 years in accordance with Sections 0.457 and 0.459 of the Commission's Rules, 47 C.F.R. following grant of the application.

The company believes that the request for long-term confidentiality is crucial to the product success in the market. Disclosure of the product internal photos will result in competitive harm as it will lead our competitors to insights into both designs and manufacturing techniques.

We are therefore requesting to consider a long-term-confidentiality of the internal photos of the Genius SB capsule for the duration of 10 years.

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

Internal photos

- **Explanation of the degree to which the information is commercial or financial or contains a trade secret or is privileged.**

This information is contained in the internal photos of a sealed device designed for ingestion by humans. As such this material is treated as highly confidential.

- **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 engineering personnel who have designed the equipment and manufacturing processes. Disclose would also offer competitors additional unwarranted insight into the state of the product development thereby allowing such competitors an advantage that would not be available to Given Imaging.

- **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 10 years. While improvements in design are likely to be made during this period, disclosure of the photos 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.

We understand internal photos are typically not held confidential but may be eligible for confidentiality under the special conditions. The company believes the information provided below complies with the requirements of the special considerations described in the applicable KDB:

- **Our Pillcam™ Genius SB capsule which is the subject of this filing is not available for general public to order, is it a prescription device.**

The Genius SB capsule is a single-use disposable, ingestible capsule intended to acquire images during natural propulsion through the digestive system. As such, Given Imaging Inc., has gone to great lengths in the design process to encapsulate the inner circuitry and to protect the design details of our product.

All internal components of the capsule, including the circuit board, are encapsulated in a biocompatible plastic case and are not accessible to the user.

The plastic case consists of two parts that go through adhesion and are then laser welded to ensure all components are properly sealed. The final design undergoes routine testing to ensure the integrity of the capsule and the strength of the bond.

- The device is a prescription only device and cannot be obtained as an off- the-shelf product. As such, it is only provided to the patient under prescription by a physician. The internal components of the device are not accessible to the public as the capsule is sealed and undergoes routine testing to ensure the sealing strength. Furthermore, the capsule is excreted from the body by bowel movement and is in a biohazard state (as it comes in contact in bodily fluids, including feces).  
No access is provided to anyone outside of the manufacturing process pertaining to the inner workings of the product.
- Information regarding internal photos is not released to the public, the product cannot be obtained by the public (it is a prescription only device), and no access is provided to anyone outside of manufacturing process. Measures were taken in the design state to prevent access to internal circuitry. In addition, the capsule is single-use and is propelled by natural peristalsis until excreted whole by bowel movement.
- The device is inaccessible to the general public, as it is a prescription only device, not serviceable nor does it have its inner components and circuitry available to the public.
- For practical reasons it would be impractical to require NDA's from patients as this is likely to be in the multiple thousands and would require uploading to the FCC every time a patient submits one which would then require special action on the part of the FCC.
- **The only ones who have access to the photos is our manufacturing facility where product is manufactured.**

Respectfully,

DocuSigned by:  
  
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Avishag Metzer  
Senior Regulatory Affairs Manager  
Given Imaging