



May 22nd, 2017

Equipment Authorization Branch
Federal Communications Commission
Columbia, MD 21046

Re: Given Imaging Request For Non-Routine Long-Term Confidentiality
FCC ID No.:O8PCAPSH-3

Ladies and Gentlemen:

Given Imaging 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 confidentiality is sought**
 1. **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.

Information regarding internal photos is not released to the public, the product cannot be obtained by the public, no access is provided to anyone outside of manufacturing process pertaining to the inner workings of our product.

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

It goes through several steps to secure our intellectual property and prevent access of the inner components. All components are contained in high tensile force two-dome shaped large pill-side encapsulating cylinder made of biocompatible, pH-resistant material.

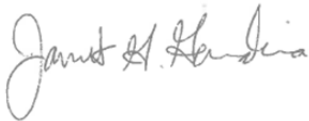
During the design stage the cylinder first goes through a bonding adhesion process and then a welding process to ensure all inner workings are properly sealed. It is with all this in mind that we are requesting the agency grant our request, no access is provided to anyone outside of manufacturing process pertaining to the inner workings of our product. Having the photos released on the FCC's website would compromise the work we have worked so hard to protect.

We understand internal photos are typically not held confidential, but may be eligible for confidentiality in certain circumstances. Confidentiality for this information may be granted in the following circumstances: Internal photos of a non-consumer device may be held confidential if the device is not accessible to the general public.

- Our Pillcam™ capsule which is the subject of this filing is not available for general public to order, is it a prescription device. Physicians perform the required procedure in the medical environment.
- Information regarding internal photos is not released to the public. Measures were taken in the design state to prevent access to internal circuitry. Product is single use.
- 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.

Should you have further questions, please feel free to contact me directly at (408) 992-1632 or janet.gavidia@covidien.com

Sincerely,



Janet Gavidia

Medtronic

Program Manager, Regulatory Affairs | RF
On Behalf of Given Imaging
Email: janet.gavidia@covidien.com