

## **REVISED REQUEST FOR CONFIDENTIALITY**

Given Imaging, Ltd. ("Given"), pursuant to 47 C.F.R. § 0.459, requests confidential treatment for its application seeking equipment certification for Given's M2A™ Capsule, an ingestible imaging device, that is part of the Given® Diagnostic Imaging System designed to acquire images of the small intestine in order to detect disorders and abnormalities of the small intestine. Confidential treatment is sought for all schematics, diagrams and technical descriptions as they pertain to both the M2A™ Capsule specifically and the Diagnostic Imaging System generally, and it is requested that the sales projections which were submitted as part of the application be deleted upon grant.

The information submitted in support of the application is highly commercially sensitive. The medical imaging field is competitive, and the M2A™ Capsule represents a significant technological advance. Disclosure of the above information would result in competitive harm by granting Given's competitors access to highly sensitive and/or proprietary information. Given has not generally made the information submitted with the application available beyond the extent necessary to attract financing, to construct and test the device, and to seek necessary government approvals. Notably, the materials fall within exemption 4 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4), which pertains to trade secrets and commercial or financial information, and allows an agency to withhold such business competitive information from public disclosure.

In view of the fact that the Commission keeps the whole of an equipment authorization application confidential until a grant is issued, confidential treatment for the portions of the application specified above is requested after a grant issues until such time as Given makes the above information publicly available. This duration of confidential treatment is necessary to protect any first-to-market or other competitive advantage that may be held by Given.