

Medtronic

Endoscopy Operating Unit

Given Imaging Inc.
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Mansfield, MA 02048
USA

www.medtronic.com

Request for label exemption for FCC ID: O8PPATCH

PillCam Genius Link Device

Given Imaging Inc. is requesting to place the FCC ID: O8PPATCH of the PillCam Genius Link Device on the package level of the kit which includes the device, and not directly on the device itself, since there is no label on the device and it is intended for single-use.

The PillCam Genius Link Device is part of PillCam Genius SB Endoscopy kit which includes a capsule as well. The kit supports the capsule endoscopy procedure which enables visualization of the gastrointestinal tract.

The Genius Link Device is a single-use data recorder that is worn by the patient throughout the PillCam Genius procedure. The device includes an adhesive layer that attaches to the skin of the patient's abdomen. At the end of the procedure, the Link Device is removed and returned to the clinic. After the data is downloaded from the link device it is disposed.

The company therefore intends to have the FCC ID of the Genius Link Device listed on the kit labels, as shown in the figures below.

The FCC ID will also appear on the insert provided with each kit.

Sincerely,

DocuSigned by:

F6EBD4306390484...

Avishag Metzer

Senior RA manager, Given Imaging

Figure 1. Example of label placed on the primary packaging of the kit

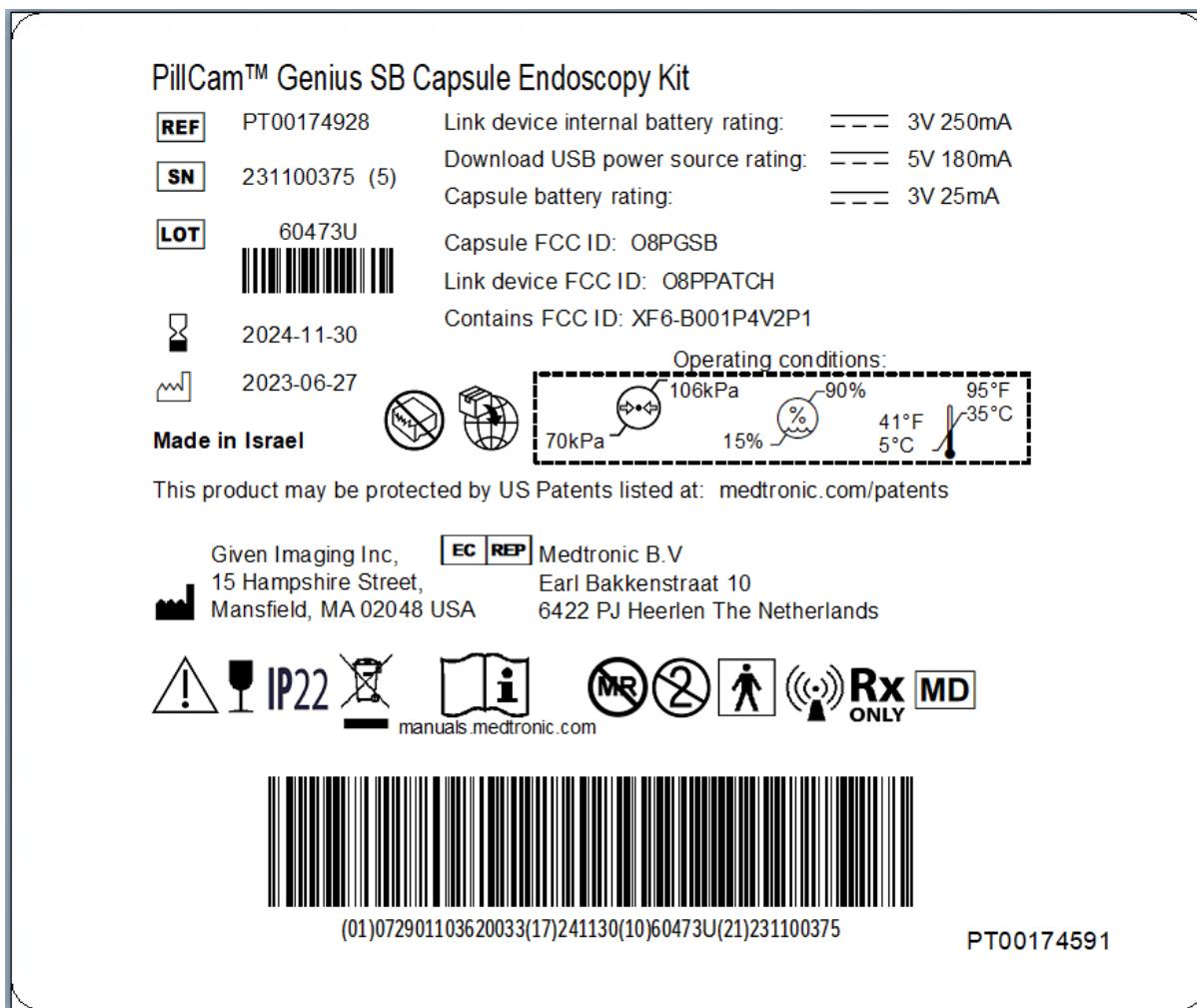


Figure 2. Example of label placed on the secondary packaging of the kit (box)

