



New Device Approvals

Given® Diagnostic Imaging System K010312



Product Name: Given® Diagnostic Imaging System

Manufacturer: Given Imaging Ltd.

Address: Oakbrook Technology Center, 5555 Oakbrook Parkway, Suite #355, Norcross, Georgia, 30093

Clearance Date: August 1, 2001 (Approved Evaluation of Automatic Class III Designation)

What is it? A capsule that contains a tiny video camera, lights, transmitter and batteries. The capsule is swallowed and passes through the digestive tract, where it takes video pictures of the small intestine (small bowel) and relays them to a small recorder that attaches to the patient's belt. The capsule, which is a little more than one inch long and a little less than one-half inch wide, is as easily swallowed as most common capsules, caplets and tablets.

How does it work? The whole capsule passes through and comfortably out of the body in about eight to 72 hours. There is no wiring. The pictures are sent by radio frequency to the recorder and are then evaluated by the patient's health care provider.

Are there limits on patient movement? The patient can walk around, but should not bend or stoop or do anything that is physically hard or involves vigorous movement.

When is it used? It is used to view the inside of the small bowel when there is chronic or unexplained rectal bleeding or there is blood in the stool and when small bowel disease is a concern. It is used only after the patient has received other procedures to view the inside of the small bowel.

What will it accomplish? It takes pictures of the entire small bowel. Endoscopes can only see the upper part of the small bowel.

When should it not be used? It should not be used in people who have

- A cardiac pacemaker
- Other implanted electromagnetic devices
- An intestinal blockage
- A significantly narrowed small bowel
- An abnormal connection between the bowel and another organ

An x-ray exam of the small bowel should be done if there is concern that it may be too narrow for the camera.

What should be avoided? Avoid anything that causes electromagnetic interference (EMI), such as ham radios and magnetic resonance imaging (MRI) machines, because this can cause the pictures to be lost.)

Additional information: More details regarding this device approval can be found at:
<http://www.fda.gov/cdrh/pdf/k010312.pdf>

FDA Talk Papers: <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01094.html>

[[Accessibility](#)]

(Updated 8/21/2001)