

T. Rowe Price Associates, Inc.

P.O. Box 89000
Baltimore, Maryland 21289-9999
100 East Pratt Street
Baltimore, Maryland 21202
410-345-2000

September 25, 2000
Documents Management Branch (HFA - 305)
Food and Drug Administration
5630 Fisher Lane Rm. 1061
Rockville, MD 20852

RE: Docket No. 00P-0788 and 00D-1455

To Whom It May Concern:

This letter is being submitted in response to the FDA's request for comments relative to the recent Federal Register publication of the Notice of Panel Recommendation to reclassify the Totally Implanted Spinal Cord Stimulator for Pain Relief.

I am an investor in the medical device industry. It is my belief that the FDA notice of panel recommendation and special control guidance document adequately addresses the concerns regarding the assurance of safety and effectiveness for the IPG device for pain relief. The risk to health of lead migration, device failure, tissue reaction, skin erosion, surgical, procedural risk, EMC and MR compatibility concerns are appropriately identified and characterized by the FDA and their panel.

I believe that the Special Control Guidance for Premarket Notification for Totally Implanted Spinal Cord Stimulators for Pain Relief covers the elements necessary to allow the medical device industry to design and manufacture safe and effective IPGs for pain relief. This guidance will be useful to both industry and the FDA to provide equivalent assurance of safety and effectiveness when premarket notifications are submitted to the FDA for these types of devices. The proposed labeling, technological reporting, device testing and manufacturing requirements appear to be consistent with what is necessary to address the design, manufacturing concerns for this type of device.

I commend the FDA for your efforts to reclassify the IPG device to a Class II status. Over-regulation of this device has long been overlooked. This is definitely a step in the right direction by the FDA to reduce the burden and speed the process of getting new IPGs to market. Competition breeds innovation, and I believe that this reclassification will ultimately help to speed the innovation that is still needed in this market. I also believe that the reclassification will provide an added incentive for other manufacturers to enter this exciting market segment.

Sincerely,



Christina Wyskiel
Equity Research Analyst
T. Rowe Price Associates

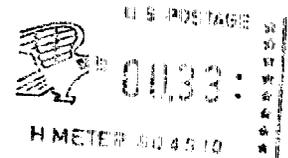
00D-1455
00P-0788

1 3 1 9
00
SEP 28
A10:23

C 2
T. Rowe Price 

T. Rowe Price Associates, Inc.

P.O. Box 89000
Baltimore, Maryland 21289-9999



Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane Rm. 1061
Rockville, MD 20852



20857/0001 