New Device Approvals

Optical Biopsy™ System

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	Optical Biopsy™ System
Manufacturer:	SpectraScience™, Inc.
Address:	14405 21st Avenue N., Suite 111, Minneapolis, MN 55447
Approval Date:	November 14, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p990050a.pdf

What is it? The Optical Biopsy™ System includes a laser light, a long fiber that the light passes through, and a computer that analyzes the light given off by growths (polyps) in a patient's lower bowel after the laser light is shined on them. The Optical Biopsy System™ helps a physician understand how important any growths found are while examining the inside of a patient's lower bowel (sigmoidoscopy or colonoscopy).

How does it work? A physician inserts the long fiber of the Optical Biopsy System through the instrument used in the bowel examination (sigmoidoscope or colonoscope) and points it at a growth that looks harmful. The growth absorbs the laser light and returns light back through the long fiber to the computer which analyses the returned light. The system's computer then indicates whether or not the growth is harmful and may become cancer, using patterns of light returned from harmful and normal growths found in previous patients.

When is it used? Physicians usually remove all growths that look harmful and examine them with a microscope. If a growth is smaller than one centimeter across and it does not look harmful, the physician may use the Optical Biopsy System™ to check the decision to leave the growth in the bowel.

What will it accomplish? When a physician decides to not remove all growths, the device can help identify those growths that should be removed and examined.

When should it not be used? Physicians should not use the device instead of their judgment in deciding which growths to remove. Moreover, physicians should not use it on patients who have blood clotting problems, conditions that prevent the removal of growths in the bowel, or familial polyposis. Familial polyposis is the condition where many growths develop, starting at puberty, that might become cancer.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p990050.html

FDA Talk Paper: http://www.fda.gov/bbs/topics/ANSWERS/ANS01054.html
CancerNet, National Cancer
Institute:http://cancernet.nci.nih.gov/Cancer_Types/Colon_And_Rectal_Cancer.shtml