APPENDIX D - SUMMARY OF SAFETY AND EFFECTIVENESS

Summary of Safety and Effectiveness for the Eclipse Model 2000™

Intended Use

The Eclipse 2000™ is intended for use in general surgery, including thoracic and abdominal surgeries. This includes the incision, excision, vaporization or coagulation of soft tissue and firm cartilage:

- cholecystectomy
- lysis of adhesions
- herniorrhaphy
- sessile polyps of the intestine and colon
- hemorrhoidectomy
- condyloma
- appendectomy

Description of Device and Method of Operation

The Eclipse Model 2000™ laser system is designed to be easy to operate and user-friendly. It features a security keyswitch and simple one-button start-up. Energy output is controlled by the Power thumbwheel adjustment. Energy is delivered through the Eclipse delivery system only when:

1) the laser is in Ready mode,
2) the Foot Pedal is depressed, and
3) the delivery system is properly installed in the laser aperture.

A variety of disposable fiber optic delivery systems in a range of sizes, designs and configurations is available from Eclipse. A fiber optic delivery system must be used to delivery laser energy to the treatment site.

Safety Information

Prior to turning the laser system on, all persons in the operating room, including the patient, should be wearing protective eyewear suitable for holmium laser energy

IT IS ESSENTIAL THAT THE PHYSICIAN AND ATTENDING STAFF BE TRAINED IN ALL ASPECTS OF THE LASER PROCEDURE. NO PHYSICIAN SHOULD USE THESE LASER PRODUCTS FOR THE ABOVE STATED INDICATIONS WITHOUT FIRST OBTAINING DETAILED INSTRUCTIONS IN LASER USE

Precautions such as careful assessment of the target and surrounding tissue during treatment and use of appropriate power and pulse duration should be taken.

Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser power or the application of power for excessive periods of time.

Use the laser only on tissues that are fully observable. Do not use the laser if the desired operating field is obscured.

Aim the laser beam only at tissues intended for treatment otherwise damage to surrounding tissues may result.

Flash fires can occur. Nonflammable anesthetics should be used. It is recommended that oxygen levels in the direct operative area be below 30%.

No clinical information or experience concerning the use of holmium laser systems on pregnant women or nursing mothers is available.

Patients who experience discomfort during laser treatment may require analgesics.

There is no guarantee that treatment with the holmium laser will entirely eliminate the disease entity. Repeat treatment or alternative therapies may be subsequently required.

Alterations in surgical approach or technique may be required to accommodate laser use.

Physicians should be thoroughly trained and proficient in all aspects of arthroscopic, endoscopic, or fluoroscopic surgery prior to using the laser through an arthroscope, endoscope, or fluoroscope, keeping in mind that depth of perception through an these devices is distorted. The physician must learn to rely on both the visual and tactile feedback of the contact delivery system.

Any clinical use of a holmium laser system not in accordance with indications for use included in the system labeling, unless specifically exempt, is subject to the provisions of 21 CFR Part 812, the Food and Drug Administration's investigational device exemption (IDE) regulations.