

Mr. Sullivan informed us that he designed the "beam shaping" mechanism that is used to control the overall diameter of the beam (the Iris), and the slit width and slit diameter (used for treating astigmatism). He also stated that he developed the software for controlling that mechanism.

On 6/25/97, I was able to observe Mr. Sullivan calibrating one of the excimer lasers, at a local client's office. During that time, Mr. Sullivan informed me that he developed all of the "beam controlling" software programs, the calibration programs and the safety and alarm shut off software programs, that are in all of the devices he has assembled. He also stated that he is responsible for installing all of that software.

OPERATIONS AND EQUIPMENT:

Mr. Sullivan informed me that his procedures are the same for each device he builds/assembles. He stated that he first contracts with the physician, and the physician will then tell Mr. Sullivan exactly what capabilities they want for the laser device. Mr. Sullivan will then provide the physician with the hardware specifications for each component, and will also recommend the component manufacturer for ordering each component. He stated that he would then assemble the device in the physician's office, either supervising others or completing the assembly himself. He informed me that in most cases, that his contracts include a two year service agreement.

MANUFACTURING PROCEDURES:

Mr. Sullivan stated that he did not have any standard procedures for assembling the device. He stated that the device components are delivered to each physician's office, where he then assembles the complete excimer laser. He informed me that he will then test the laser, but that he does not have any performance specifications, written assembly instructions or quality control tests. The physician is then able to use the laser, after a training period that is supervised by Mr. Sullivan.

INFORMATION REQUESTED BY CDRH/OC:

1. Determine the firm's current activities and document the relationships between this firm and other firms.