

physicians that have contracted with the firm for excimer lasers.

HISTORY OF BUSINESS:

Mr. Sullivan stated that he started the business shortly after the termination of his employment with the firm [REDACTED] which had been started by a [REDACTED]. He informed me that while an undergraduate, he answered an employment advertisement at the [REDACTED]. Mr. Sullivan explained that [REDACTED] hired him to develop the hardware and software for shaping an excimer laser beam for use in ophthalmological surgery. Mr. Sullivan explained that he developed the system on his own, and that the development work for the firm's (ExSull, Inc.) current excimer laser's software is based on his work at [REDACTED]. He stated that shortly after they had demonstrated the first surgery [REDACTED] on a patient, [REDACTED] started the company [REDACTED] to build Excimer lasers for eye surgery.

Mr. Sullivan stated that he was terminated by the president of [REDACTED]. He explained that at the time he did not have the financial requirements to start his own business, however, physicians were contacting him to help build excimer lasers. He stated that he called the FDA and was sent material relating to the building of "custom devices", and that the FDA person he had spoken to over the telephone assured him that "it was okay to build them in the Doctor's office". Mr. Sullivan informed me that after he had this information verified, by lawyers and former FDA employees, he started to build an excimer laser for [REDACTED]. In this case (and subsequent cases), Mr. Sullivan stated that he would receive basic requirements for the lasers output, from the physician, and would then work out the design specifications with the physician, through a number of conversations, both in person and over the telephone. Mr. Sullivan explained that he always has the physicians order the device components, which are delivered directly to the physician's office, and he will then come and assemble the device in that office. The firm was incorporated in Delaware, in 1993.

Mr. Sullivan stated that his business hours are quite irregular. He said he could go weeks without working on any of his client's excimer lasers, and other times when he can be weeks at their offices. Mr. Sullivan stated that since he keeps these irregular hours and his business office is located at his residence, he requests that any FDA Investigators notify him prior to any visits to the firm (ExSull, Inc.).