Mr. Sullivan stated that none of his clients use his name in any advertisements for the excimer laser devices, or for the ██████ technique. **Mr. Sullivan did state that he will be publishing an article with a Dr. Herbert Nevyas, regarding the use of the ExSull, Inc., excimer laser for treatment of a patient with an irregular cornea, due to an eye injury.**

5. Determine whether Mr. Sullivan (or his clients) have submitted IDE(s) for the devices he has built (and his level of involvement in helping the doctors submit the IDEs for the devices).

Mr. Sullivan informed Mr. Despins and myself, that as of 4/9/97, only the following Doctors had submitted IDEs:

He also stated that he is the technical consultant for most of the IDEs filed by physicians using the ExSull, Inc., excimer laser. He stated that he is aiding a user group, headed by A██████████████, that is helping all of the physicians who are submitting IDEs. **He informed me that he did all of the drawings for the IDEs, both the two dimensional and three dimensional drawings.** During the inspection, he showed me the IDE documentation of ██████████ During my viewing of the IDE, **he demonstrated that he was extremely knowledgeable regarding all of the technical information, and of the additional technical requirements that the FDA was requesting.**

6. What are the capabilities of the devices? How were the specifications for the devices developed?

Mr. Sullivan informed me that all the information, regarding capabilities of the laser, is contained in the IDE documents that have been submitted to the FDA (one for each site/device), and that I should extract the information from there.

Mr. Sullivan did explained how the specifications for each device are developed. He stated that each physician would provide him with the basic requirements for the excimer laser. These include: output energy, beam shape, beam size and slit variability. Mr. Sullivan explained that he would then provide the physician with the specifications for each