

SAMPLES COLLECTED:

None.

VOLUNTARY CORRECTIONS:

None.

COMPLAINTS:

Mr. Sullivan stated that complaints regarding the surgery on patients, are handled the individual physician. He stated that he does not keep any repair or service log books, or a records of any complaints regarding the performance of the laser, by the physicians.

RECALL PROCEDURES:

Mr. Sullivan stated that he had no procedures for recalling any of the devices, or the software component.

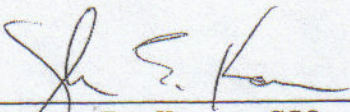
PROMOTION AND DISTRIBUTION:

Mr. Sullivan stated that he does not promote or advertise his firm's building excimer lasers. He explained that all of his clients had contracted with him, after being referred by other physicians.

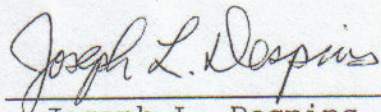
REFUSALS:

Although Mr. Sullivan was cooperative, for the most part, he would not provide me with any documents that would name a "client" of his. He stated that only if the FDA would have to provide him with a letter of indemnification, would he allow me to review his current "business" documents. Mr. Sullivan did verify the names of some of his clients, as I read him a list of physician names.

In addition, Mr. Sullivan refused to sign or even listen to the affidavit, that summarized all the information he had supplied during the inspection.



Steven E. Kane, CSO



Joseph L. Despina, CSO