

that he is not a device manufacturer. He informed me that he is only a consultant, and that each device he assembles is considered a "Custom Device". **He confirmed that he did not have any medical device manufacturing records, such as Master Device Record or Device History Record.**

During discussions with management, I explained to Mr. Sullivan that the FDA did consider him a manufacturer, in that he is responsible for the design specifications (including hardware and software), the assembly and calibration for each of the devices. Mr. Sullivan responded that he still feels that each excimer laser is a "custom device", and that he is not a manufacturer, therefore, the GMPs do not apply.

**a) The firm does not maintain Device Master Records or Device History Records.**

I asked Mr. Sullivan if the firm had a Device Master Record or Device History Record. He responded that he considers himself a consultant, and that he does not keep any records of design specifications, manufacturing specifications or a device History Record. He stated that each of the physicians might have any documentation for the specifications or design, for their device.

**b) Does not maintain complaint files.**

During the inspection, Mr. Sullivan stated that **complaints were handled by the physicians, and that he was not responsible for any patient complaints.** He also stated that he did not have any records relating to servicing the devices or complaints related to performance. He explained that any service log books are maintained by the individual physicians.

During discussions with management, Mr. Sullivan had no comment about the observation. He did ask what the regulations state about the responsibility of a manufacturer for servicing a device, if the client reneged on payments and severed the contract agreement. He also asked what the regulations state about the length of time that a manufacturer is responsible for a device - is there a time limit? I told Mr. Sullivan that I was not sure, but that I would obtain an answer.

**c) Does not maintain written manufacturing specifications and processing procedures.**

During the inspection, Mr. Sullivan stated that he had