[redacted]

**** This list had been faxed to the district, from CDRH, on 4/11/97 (Attachment 6).**

As mentioned, Mr. Sullivan is responsible for design specifications, recommending component manufacturers and assembling the device, but that some of the assembly and specifications may be done by the physician. One area that **Mr. Sullivan is solely responsible for, is the development and installation of the software that controls and calibrates the "beam shaper".** He stated that **the calibration software program includes a self-diagnostic program and a manual calibration program.** He informed me that **operating the manual calibration program for adjusting the controller, is only done by himself or someone he can train at each facility** (not necessarily the physician).

3. Determine if Mr. Sullivan has built or is contracted to build additional units. Determine his level of involvement.

Mr. Sullivan informed me that he has not contracted to build any additional units, since he assembled the device for [redacted] in October 1996. On 6/26/97, Mr. Sullivan showed me a copy of an IDE for that same client, [redacted] Mr. Sullivan explained that he was working on the document, **and an examination of the IDE showed that the unit had been used to treat at least [redacted] patients, without an approved IDE.** Mr. Sullivan would not allow me to copy this document, and stated that the FDA already has this IDE on file.

4. Obtain copies of any promotional material involving Mr. Sullivan and the building of these laser devices.