ExSull, Inc.
319 Lombardy Road
Drexel Hill, PA 19026
SEK 4/9 & 6/25-27 (97)

SUMMARY OF FINDINGS:

Inspection of a Medical Device manufacturer of excimer lasers, ExSull, Inc., 319 Lombardy Road, Drexel Hill, PA 19026, was conduct as per request from CDRH/OC, to ascertain the firm's current activities regarding the manufacture of excimer lasers for use in ophthalmological (LASIK) surgery. The inspection was conducted according to PHI-DO Assignment #97-0147 and CPGM 73820.830L. Joseph L. Despins, CSO, accompanied me on 4/9/97, but was not present during the any of the other inspectional dates. I (Steven E. Kane, CSO) have written the entire EIR, and Investigator Despins has checked the accuracy of the EIR, for only those parts of the EIR that relate to the 4/9/97 inspectional date (including parts stating "we" or "us").

Previous inspection, 5/16/96, was a follow up to a Warning Letter issued on 8/17/95. The Warning Letter informed the firm that the FDA considered ExSull, Inc., to be a manufacturer of a Class III medical device, that was both adulterated and misbranded, in that there were no approved PMA or IDE for any of the devices and that the firm itself was not registered as a medical device manufacturer. The inspection determined that the firm continued to service the excimer laser devices for their previous customers, but had not contracted with any new customers, since the receipt of the Warning Letter. An FDA-483 was issued and the inspection was classified [redacted]

The current inspection revealed that the firm is responsible for the overall design specifications and assembly for each excimer laser, and that the firm has also developed the software program, that controls the "beam shaping" or "sculpting" mechanism (also developed by the firm). The inspection found significant GMP violations, including: no software validation data for the software program specifically developed (by the firm) for controlling the "beam shaping" or "sculpting" mechanism; failure to maintain Device Master Records or Device History Records; failure to maintain written manufacturing specifications and processing procedures; and failure to maintain complaint files. An FDA-483 was issued regarding these observations.

In addition, the inspection determined the following: that the firm maintains they have not contracted with any physicians since the completion of the last device, in October 1996; the firm continues to provide service for the [redacted] physicians still under contract; that Mr. Sullivan has recently developed specialized software (for at least one client), to treat an [redacted] caused by [redacted] and verified a list of

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]. [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.).

ExSull, Inc.
319 Lombardy Road
Drexel Hill, PA 19026
SEK 4/9 & 6/25-27 (97)

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES:

On 4/9/97, Joseph L. Despins, CSO & myself presented our credentials and an FDA-482 was issued to **Edward J. Sullivan**, President, ExSull, Inc., Drexel Hill, PA on the premises of LaserLink, 108 Chesley Dr., Madison Bldg., Media, PA 19063. The firm's actual office is located at 319 Lombardy Road, Drexel Hill, PA 19026., but Mr. Sullivan was very adamant that we not meet at that location, since this site is also his residence and our presence disrupts his family life. He suggested that Mr. Despins and myself meet him at another firm, which he is a part owner, LaserLink, an internet service provider firm. Repeated attempts to schedule a subsequent meeting with Mr. Sullivan (via my leaving numerous messages on his voice mail) were unsuccessful. Mr. Sullivan would not commit to a date and time, when he returned my repeated phone calls, and in some instances did not even return my phone calls. Only after inadvertently meeting him at one of his client's (on 6/25/97), did he then agree to see me at his ExSull, Inc., Drexel Hill location. On 6/26/97, I presented my credentials and issued another FDA-482, Notice of Inspection, to Mr. Sullivan. On 6/27/96, an FDA-483 was issued to Mr. Sullivan, and was present during discussions with management.

GUARANTEES & LABELING AGREEMENTS:

Mr. Sullivan maintained that there are no labeling agreements, and that the only labeling on the devices is that required by any regulations for warning or cautionary labeling for the safe operation of lasers.

TRAINING PROGRAM:

Mr. Sullivan stated that he is the only employee of the firm. He stated that he has not had any formal training in GMP regulations.

RAW MATERIALS AND COMPONENTS:

Mr. Sullivan stated that all of the devices (except the first excimer laser at the Kremer Eye Associates) **have a** [redacted] In addition, he stated that most of his client's had purchased the integrated laser enclosure from [redacted]

Mr. Sullivan informed us that he designed the "beam shaping" mechanism that is used to control the overall diameter of the beam (the Iris), and the slit width and slit diameter (used for treating astigmatism). He also stated that he developed the software for controlling that mechanism.

On 6/25/97, I was able to observe Mr. Sullivan calibrating one of the excimer lasers, at a local client's office. During that time, **Mr. Sullivan informed me that he developed all of the "beam controlling" software programs, the calibration programs and the safety and alarm shut off software programs, that are in all of the devices he has assembled. He also stated that he is responsible for installing all of that software.**

OPERATIONS AND EQUIPMENT:

Mr. Sullivan informed me that his procedures are the same for each device he builds/assembles. He stated that he first contracts with the physician, and the physician will then tell Mr. Sullivan exactly what capabilities they want for the laser device. Mr. Sullivan will then provide the physician with the hardware specifications for each component, and will also recommend the component manufacturer for ordering each component. He stated that he would then assemble the device in the physician's office, either supervising others or completing the assembly himself. He informed me that in most cases, that his contracts include a two year service agreement.

MANUFACTURING PROCEDURES:

Mr. Sullivan stated that he did not have any standard procedures for assembling the device. He stated that the device components are delivered to each physician's office, where he then assembles the compete excimer laser. He informed me that he will then test the laser, **but that he does not have any performance specifications, written assembly instructions or quality control tests.** The physician is then able to use the laser, after a training period that is supervised by Mr. Sullivan.

INFORMATION REQUESTED BY CDRH/OC:

1. Determine the firm's current activities and document the relationships between this firm and other firms.

Mr. Sullivan stated that he has an equity interest in two other firms, LaserLink, Inc., and Solas, Inc. Laserlink is an internet service provider, and a visit to the firm, by Joseph Despins and myself, confirmed that the firm was not connected to ExSull, Inc. At that time, he also stated that he has no equity interest in [redacted]

Mr. Sullivan stated that he is the President of Solas, Inc., and that he runs the day to day activities of that firm. He said that the firm represents [redacted] products, for sale of laser systems for cleaning. He informed us that the co-owner of Solas, Inc., is vice-president of sales, and that any involvement by Mr. Sullivan in a sale, would depend on the nature of the sale. He would not elaborate on that statement, but explained that it means that he is not involved in every sale. I asked Mr. Sullivan how he could possibly run the day to day operations of Solas, Inc., when he is involved in so many other enterprises. He replied that the excimer laser business is erratic in nature and thus allows him to pursue other ventures. He also stated that the he utilizes the fax, pager, laptop PC, and other electronic communication devices in order to run the day to day business of Solas, Inc. In addition, **Mr. Sullivan stated that he owns shares in Laser Sight, Inc.** - see Attachment 7.

2. Document the contracts for the laser devices he has built. Determine the level of his involvement/responsibility in the building of each laser device. Obtain DOC samples if possible.

Mr. Sullivan would not provide me with copies, or allow me to visually review any of the contracts for his "clients". He stated that he would only allow me to examine those contracts on the condition that the FDA would provide him with a letter of indemnification. He explained that he was concerned about any potential lawsuits, involving his clients, that might occur as a result of a client's name being made public (through the FOI process, as concerns the EIR). He told me that he would not provide me with any written verification or list of the physician's names, but that he would verbally verify any physician's name. **I verbally read a list of physician's names to Mr. Sullivan, and he responded to each of the names, stating either that the physician was not a client or that they were his client. The following are those physician's who Mr. Sullivan verbally said "yes" or "yes they are a client of mine", as I read the list:**

1) [redacted]
2) [redacted]

[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.

Mr. Sullivan stated that none of his clients use his name in any advertisements for the excimer laser devices, or for the [redacted] 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:

[redacted]

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 [redacted], 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 [redacted] 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

component and a suggested component supplier, for each of them. **According to Mr. Sullivan, this entire process (the exchange of laser beam requirements and the design specifications) is all done via telephone or personal visits, and he does not have any written records of the design specifications. He stated that each individual physician should have those records.**

7. Determine whether Mr. Sullivan or his clients have submitted laser product reports or complied with the Radiation Health requirements for the devices he has built.

Mr. Sullivan informed me that he does not know if his client's have submitted laser product reports, but he thinks they have all complied with the Radiation Health requirements. He stated that this was the responsibility of the individual physician, to submit the reports and/or comply with the Radiation Health requirements. Any records regarding these issues would be kept at the individual physician's office.

8. Determine whether Mr. Sullivan is aware of any significant undercorrections or overcorrections or other injuries caused by the use of these laser devices. How is Mr. Sullivan handling complaints/problems with the devices.

During the inspection, on 4/9/97, Mr. Sullivan stated that he knew of no injuries with the device. He did say that in theory the laser would have some patients possibly experiencing overcorrection, but that the majority would experience a slight undercorrection, which might require additional treatment. In addition, he explained that there has been no hazing or scaring, with the devices. **He stated that the physicians handle all of the complaints from the patients,** and that he is not aware of any major complications. He did mention one patient who is suing one of his client's, but that the device did not cause the injury. He stated that a second physician, one that the patient went to for a second opinion (after the initial [redacted], did the alleged injury.

On 6/27/97, Mr. Sullivan elaborated that the case of the law suite occurred in April 1995, and involved a woman who was [redacted] Mr. Sullivan stated that a correction of [redacted] requires a much longer recovery time. He explained that this is why most of the physicians will undertake this amount of correction in "stages". He stated that the patient returned to the physician who had performed the original [redacted] complaining of still blurry

vision. She was informed that she should wait for the full recovery time, after which, further surgery could be attempted. Mr. Sullivan explained that the patient did not wait the full time, and went to the second physician, who used a [redacted] to remove a [redacted] disc of the cornea, for pathology screening. That patient finally had to have a corneal transplant.

OBJECTIONABLE CONDITIONS AND DISCUSSIONS WITH MANAGEMENT:

1. The firm does not have any software validation data for the software program specifically developed (by the firm) for controlling the "beam shaping" or "sculpting" mechanism (sometimes referred to as a "Controllable Iris/Slit with Laser Pulsar", and also designed by the firm), that the firm sold to and installed in approximately [redacted] Ophthalmological Excimer lasers located in Physician's offices, sometime between August 1994 and October 1996.

During the inspection, Mr. Sullivan informed both myself and Investigator Despins that he personally developed the software that controls the "beam shaper". Later in the inspection, Mr. Sullivan informed me that he designed the hardware for the "beam shaper" or "beam sculptor", as well as, the software that controls that hardware. **He stated that his program was written in [redacted] and that three versions have been made, of that software. He informed me that he had no documentation or procedures for upgrading or changing the program (at the [redacted]. In addition, he could not provide any information regarding which of the software versions are in any of the particular devices, stating that he did not keep any of those records.** He also explained that he has not upgraded any of the earlier versions of the software program, that might be on any of the "older" devices. **Mr. Sullivan explained that he has no review or approval process for the changes to the software.** He stated that he checks the changes by comparing the source codes, between the previous version and the "changed" version, to see if the source code was changed. I asked if he then tests the software, to verify that the changes performed as intended. He stated that he did not, and that the software would be tested at the physicians office, either by himself or an employee of the physician. **He explained that the testing by the physicians concentrates on the excimer laser as a whole, and not on any of the individual software programs/components.**

During the inspection, on 6/26/97, **Mr. Sullivan stated that he did not test the software versions of his program**

prior to installing them on the devices desktop computer, to see if they performed as intended. He also stated that the entire software program for the "beam shaper", including the calibration and safety modules, is only about [redacted] and can be contained on one floppy disk. **He stated that he is responsible for all initial installations.** He said that (in most cases) he installs updated programs, or sends them via E-Mail to the physician for them to install. Mr. Sullivan had not tested/verified any of these methods of installation (floppy disk or E-Mail).

On 6/25/97, Mr. Sullivan and I simultaneously (and unplanned) arrived at one of his clients. Mr. Sullivan and the physician informed me that **Mr. Sullivan was there to calibrate the device. Mr. Sullivan gave his permission for me to observe the calibration procedure.** I was allowed to examine the optical compartment, including the "beam shaper" or "beam sculptor", designed by Mr. Sullivan. Mr. Sullivan would not let me photograph this part of the device. **I observed that the "beam shaper" has three motors that control the iris, the slit former and a motor for rotating the slit, once it is formed.** It resides between the second of two lenses, and the angling mirror (see Attachment 5). **In addition, I observed Mr. Sullivan utilizing a calibration program (residing on the device's/client's computer) that he confirmed he had developed.** He also stated that this calibration software, is part of the same program he developed and installs in each of the devices he assembles for his client's. **The program controls the "beam shaping" mechanism during the operation of the laser, and also contains the calibration modules. Mr. Sullivan would not allow me to have a printout of the screen, during this calibration process, nor would he provide me with any material regarding the program.**

On 6/26/97, Mr. Sullivan confirmed that the "beam shaper" is really the "Controllable Iris/Slit with Laser Pulsar", by showing him a copy of an invoice from ExSull, Inc. to a local client (that lists the "Controllable Iris/Slit with Laser Pulsar") and having him state that this is that mechanism. I then asked if the software program is installed on all of the devices he has assembled for his client's. He replied that there might be some slight variations, due to the individual requirements of the client's, but that the control and alarm functions are the same.

2. The firm does not follow GMP regulations in that:

During the inspection, Mr. Sullivan repeatedly stated

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**

no specifications or procedures for assembling the excimer laser devices. He said that he did not keep any written procedures for assembling the devices. He stated that the design specifications were all done verbally, between himself and the individual physicians.

During the discussions with management, Mr. Sullivan had no comment about the observation.

d) Does not have the above documents, readily available, for review and copying by designated employees of FDA, at a location that is reasonably accessible to FDA employees.

During the inspection, Mr. Sullivan stated that the firm's computer, used to store all of the business records, had experienced a "hard drive crash", in the winter of 1996. He explained that **consequently all records from 1994 to December 1996 have been lost.** I asked if the firm had any system for backing up data or programs. Mr. Sullivan stated that he did not have any back up system for those records. I specifically asked if he had any invoices for his clients, that mentioned the firm's "beam shaper" or software, which I stated a client had already supplied me with a copy. Mr. Sullivan replied that all of those records were lost in the hard drive crash. When I asked Mr. Sullivan if I could see the records from December 1996 to the present, he stated that he did not want to present any documents to me that would have a client's name, but that I could see his office to confirm that he did not have extensive records.

On 6/27/97, he showed me the office, located on the third floor of his residence. The office was extremely disorganized and was only (approximately) a 35' X 20' total area. The furniture in the room consisted of an L-shaped desk (with drawers), a small book shelf containing "off the shelf" software ([redacted]) and program manuals, a TV/stereo entertainment cabinet, other book shelves, a drum set. There was a copy of the IDE from [redacted] on the floor, and many loose papers on the desk. He stated that some of these loose papers were related to ExSull, Inc., but that he did not have the records I requested. There were no filing cabinets, and Mr. Sullivan stated that he did not keep records in any other location in the house. He also stated that he really didn't keep any hard copies of his business records.

During discussions with management, Mr. Sullivan had no comment about the observation.

SAMPLES COLLECTED:

None.

VOLUNTARY CORRECTIONS:

None.

COMPLAINTS:

Mr. Sullivan stated that complaints regarding the [redacted] 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

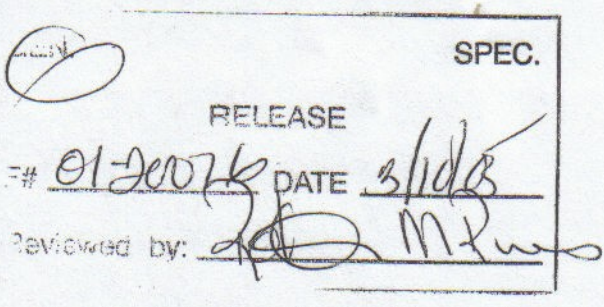
Joseph L. Despins, CSO

ATTACHMENTS:

1) FDA-482, Notice of Inspection, issued to Edward J. Sullivan, President, ExSull, Inc., on 4/9/97.
2) FDA-482, Notice of Inspection, issued to Edward J. Sullivan, President, ExSull, Inc., on 6/26/97.
3) FDA-483, Summary of Objectionable Conditions, issued to Edward J. Sullivan, President, ExSull, Inc., on 6/27/97.
4) Affidavit, that Mr. Sullivan refused to sign.
5) Diagram of the inside of the optical unit, showing the lens placement and the "beam shaper".
6) Copy of list of physicians using excimer lasers, received from CDRH/OC, on 4/11/97.
7) Copy of a description of LaserSight, Inc., an exhibitor at an ophthalmological convention.
8) Copy of Assignment #97-0147.

Exhibits:

There are no Exhibits with this EIR, due to the unavailability of records at the firm.



DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NUMBER DHHS - PHS - FOOD & DRUG ADMINISTRATION Rm 900 U.S. Customhouse Second and Chestnut Streets Philadelphia, PA 19106-2973 (215) 597-4390

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED	PERIOD OF INSPECTION	C. F. NUMBER
TO: Edward J. Sullivan	4/9;6/25,26,27	2530807
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer	
FIRM NAME Exsull, Inc.	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 319 Lombardy Road	STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE *(Zip Code)* Drexel Hill, PA 19026	CITY AND STATE *(Zip Code)* Same	

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. The firm does not have any software validation data for the software program specifically developed (by the firm) for controlling the "beam shaping" or "sculpting" mechanism (sometimes refered to as a "Controllable Iris/Slit with Laser Pulsar", and also designed by the firm), that the firm sold to and installed in approximately [redacted] Ophthalmological Excimer lasers located in Physician's offices, sometime between August 1994 and October 1996.

2. The firm does not follow GMP regulations in that:

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

   b) Does not maintain complaint files.

   c) Does not maintain written manufacturing specifications and processing procedures. PROCEDURES. 4/29/97

   d) Does not have the above documents, readily available, for review and copying by designated employees of FDA, at a location that is reasonably accessible to FDA employees.

The observations noted in this FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the GMP regulation.

GEN. SPEC.

RELEASE

F# 01-20026 DATE 5/10/5

Reviewed by: [signature] 6/27/97

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	[signature]	Steven E. Kane, Investigator	6/27/97