DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NUMBER DHHS-PHS-FDA & 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. SEK 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 6/10/97

Reviewed by: SEK MK 6/27/97

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