

Before me, Steven E. Kane, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 903; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-8, effective April 11, 1953; and P.L. 96-86, Sec. 509, 93 Statutes at Large 966 [20 U.S.C. 3508], effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Dr. Robert W. Nevyas, M.D. in the county, and State aforesaid, who, being duly sworn, deposes and says:

except for the laser generator tube, *COMPex 201, S/N 950E4307, which was purchased from Lambda Physik, 289, Great Road, Acton, MA 01720. I have told Mr. Kane, that the Laser tube was actually ordered by Tower Technologies, which is a company I own for financial reasons. I explained that I did this to insure that Tower Technologies would always own the laser, and would be leasing it to Nevyas Eye Associates (if and when I were to sell my practice). I told Mr. Kane that Tower Technologies did not order any other laser tubes from Lambda Physik, and that I had signed a form when I purchased the laser, stating that if that laser were to be used for medical purposes, Tower Technologies would be responsible for complying with any FDA regulations.

I did not maintain any written records of the design specifications, nor did I receive any written design specifications from Mr. Sullivan. Not only was Mr. Sullivan responsible for the design of the excimer laser, he also checked all of the components when they arrived and assembled the entire excimer laser (or supervised the assembly, by others). After the excimer laser was assembled, Mr. Sullivan performed the initial calibration and validation of the excimer laser, and afterwards I performed my own calibrations. I did not keep any records of these calibrations, nor did I receive any records of calibration or validation from Mr. Sullivan.

On 6/25/97, Mr. Kane visited my office at the same time as Mr. Sullivan, who was here to verify the calibration of the diameters, slit width and slit angle of the laser treatment beam. Mr. Sullivan gave his permission for Mr. Kane to observe the calibration verification procedure. I informed Mr. Kane, that Mr. Sullivan and I were about to co-author a paper that would detail the recent treatment (6/15/97) of a patient with an eye injury, using a specialized computer program design and provided by Mr.

AFFIANT'S SIGNATURE AND TITLE

FIRM'S NAME AND ADDRESS (include ZIP Code)

Subscribed and sworn to before me at (City and State)

this day of 19

(Employer's Signature)

Employee of the Department of Health and Human Services Designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-86 effective May 4, 1980.