DOCKET #95-34

STATE OF PENNSYLVANIA | COUNTY OF MONTGOMERY

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 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Sec. 1-9, effective April 11, 1953; and P.L. 98-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer oaths, affirmations, and affidavits, personally appeared Dr. Herbert J. Nevyas, MD in the county and State aforesaid, who, being duly sworn, deposes and says:

I, Dr. Herbert J. Nevyas, MD, am the founder and President of Nevyas Eye Associates/Delaware Valley Laser Surgery Institute. I am the most responsible person at the firm, in that my signature appears on all contracts and I determine what medical procedures will be performed on our patients, by all of our medical staff.

On 4/9/97, Investigator Steven E. Kane, visited me at our office located at 2 Bala Plaza, 333 City Line Avenue, Bala Cynwyd, PA 19004, where he presented his credentials and issued me an FDA-482 Notice of Inspection. Investigator Kane requested information about the excimer laser (located in this office) that we use to treat patients having nearsightedness and astigmatism, using Laser Intrastromal Keratomileusis (LASIK) technique. I informed Mr. Kane that only my daughter Dr. Anita Nevyas-Wallace and myself use the excimer laser for treatment of patients with nearsightedness or astigmatism.

I informed Mr. Kane that I had contracted with a laser scientist Edward Sullivan, President, Exsull, Inc., in January 1995, to provide all technical assistance in the design and the assembly of the excimer laser, in my office. I explained that I had met Mr. Sullivan approximately two years ago, and had inquired about his building an excimer laser, according to my requirements. I informed Mr. Kane, that Mr. Sullivan told me that the excimer laser that he would build is considered a Custom Device, and would not be regulated by the FDA. Mr. Sullivan completed the assembly of the excimer Laser in the fall of 1995, and the first patient was treated (using LASIK) in January 1996.

I provided Mr. Sullivan with my basic requirements for the excimer laser, and Mr. Sullivan then used his engineering expertise to design the laser. He advised me about the component specifications and where to order each component. The components arrived in my office (at 2 Bala Plaza, Bala Cynwyd, PA 19004),

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____.

_____ (Employee'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. 98-88 effective May 4, 1980.