STATE OF	COUNTY OF
PENNSYLVANIA	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, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared DR. HERBERT J. NEVYAS MD 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, and 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 singed 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 kept 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 ____.

_____
(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. 96-88 effective May 4. 1980.

AFFIDAVIT

DOC97-735-546

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, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, 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:

Sullivan. This patient is not part of the patient population included in my IDE submission. I have treated a total of 252 patients, from January 1996 to the present date (6/30/97), and plan to continue to treat new patients with LASIK surgery, using the excimer laser designed and built by Exsull, Inc.

I have allowed Mr. Kane to photograph the device, and have provided him with the following documents, relating to the purchase and installation of the components and the promotional material for the excimer laser, located in my 2 Bala Plaza office:

1) A copy of Consulting Agreement, "... made and entered 1/20/95, by and between Exsull, Inc., a Delaware Corporation, of 319 Lombardy Road, Drexel Hill, Pennsylvania 19026 ... and Nevyas Eye Associates, ... 2 Bala Plaza Bala Cynwyd PA ...", signed by Edward Sullivan, President, Exsull, Inc.

2) A copy of Invoice, dated 11/8/96, from ExSull, Inc., P.O. Box 164, Drexel Hill, PA 19026, to Nevyas Eye Associates, Two Bala Plaza, 333 City Line Avenue, Bala Cynwyd, PA 19004, for Controllable Iris/Slit with laser Pulser, designed and delivered to me by Edward Sullivan.

3) A copy of Invoice No. 2220, dated 9/22/95, from Neuman Microtechnologies, 26 South Main Street #112, Concord, NH 03301, for housing and electrical/gas delivery support for laser beam generator.

4) A copy of Invoice, dated 3/4/96, from Lambda Physik, P.O. Box 60464, Charlotte, NC 28260, to Tower Technologies, 1120 Tower Lane East, Narberth, PA 19072, for communication interface.

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. 96-88 effective May 4, 1980.

AFFIDAVIT

DOCKET-785-54.

STATE OF PENNSYLVANIA | COUNTY OF MONTGOMERY

Before me, STEVEN B. 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, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, 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. NAVYAS in the county and State aforesaid, who, being duly sworn, deposes and says:

5) A copy of Invoice No. 029685, dated 9/25/95, from Lambda Physik, P.O. Box 60464, Charlotte, NC 28260, to Tower Technologies, 1120 Tower Lane East, Narberth, PA 19072, for COMPex 201 EXCIMER LASER FLUOR VE, S/N 9509E4307.

6) A copy of test results of installation, using test gases Ar, dated 9/13/95.

7) A copy of test results of installation, using test gases Kr, dated 9/13/95.

8) A copy of the ~~promotional~~ informational material, given to patients considering LASIK surgery.

I affirm that the information on this and the previous pages, is accurate, to the best of my ability. I HAVE READ, BUT WOULD NOT SIGN THIS AFFIDAVIT.

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. 96-88 effective May 4, 1980.

FORM FDA 463a (4/83) PREVIOUS EDITIONS MAY BE USED. PAGE OF PAGES.

Laser Intrastromal Keratomileusis With an Excimer Laser In The Surgical Treatment of Refractive Errors: Myopia With or Without Astigmatism

PROTOCOL
VERSION 1.0
MARCH 18, 1997

REVISION: VERSION 1.1 (JULY 19, 1997)

PROTOCOL NUMBER: **NEV-97-001**

INVESTIGATORS:

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
333 East City Line Avenue
Bala Cynwyd, Pennsylvania 19004

Anita Nevyas-Wallace, M.D.
Nevyas Eye Associates
333 East City Line Avenue
Bala Cynwyd, Pennsylvania 19004

INVESTIGATOR/SPONSOR:

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
333 East City Line Avenue
Bala Cynwyd, Pennsylvania 19004

(Signature) (Date)

Telephone: (610)-668-2777
FAX: (610)-668-1509

INVESTIGATOR AGREEMENT

Morgan v. Nevyas et al.
No. 2621 April Term 2000
Plaintiff's Exhibit 7

1. Name and address of investigator and the research facility, medical school, or hospital where the clinical investigation will be done:

2. Name and address of any clinical laboratory facilities to be used in this study:
None

3. Name and address of the Institutional Review Board that is responsible for review and approval of this study:

4. Name of any subinvestigators who are assisting the investigator in the conduct of this study:

As an investigator for this study, I agree to conduct the study in accordance with the relevant current protocol and will only make changes in the protocol after notifying the sponsor-investigator, except when necessary to protect the safety, rights, or welfare of subjects. I agree to personally conduct or supervise the described investigation. I agree to inform any patients, or any persons used as controls, that the device is being used for investigational purposes and I will ensure that the requirements relating to informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor-investigator adverse experiences that occur in the course of the investigation in accordance with 21 CFR Part 812. I have read and understood the information in the device manual and protocol, including the potential risks and adverse effects of using the device. I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments. I agree to maintain adequate and accurate records and to make those records available for inspection in accordance with 21 CFR Part 812.

I will ensure that an IRB complies with the requirements of 21 CFR Part 56, will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects. I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 812.

Signature of Investigator: _____ Date: 3/18/97

INVESTIGATOR AGREEMENT

1. Name and address of investigator and the research facility, medical school, or hospital where the clinical investigation will be done:

2. Name and address of any clinical laboratory facilities to be used in this study:
None

3. Name and address of the Institutional Review Board that is responsible for review and approval of this study:

4. Name of any subinvestigators who are assisting the investigator in the conduct of this study:

As an investigator for this study, I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in the protocol after notifying the sponsor-investigator, except when necessary to protect the safety, rights, or welfare of subjects. I agree to personally conduct or supervise the described investigation. I agree to inform any patients, or any persons used as controls, that the device is being used for investigational purposes and I will ensure that the requirements relating to informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor-investigator adverse experiences that occur in the course of the investigation in accordance with 21 CFR Part 812. I have read and understood the information in the device manual and protocol, including the potential risks and adverse effects of using the device. I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments. I agree to maintain adequate and accurate records and to make those records available for inspection in accordance with 21 CFR Part 812.

I will ensure that an IRB complies with the requirements of 21 CFR Part 56, will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects. I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 812.

Signature of Investigator: Anita Nevyas-Wallace MD Date: 3/18/97

U.S. Code of Federal Regulations

U.S. Code of Federal Regulations
TITLE 21 C.F.R. [Food and Drugs]
CHAPTER I FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H MEDICAL DEVICES
PART 812 INVESTIGATIONAL DEVICE EXEMPTIONS
Subpart A General Provisions

[Previous Document in Book] [Next Document in Book]

21 C.F.R. § 812.7 **Prohibition of promotion and other practices.**

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:

(a) Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.

(b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.

(c) Unduly prolong an investigation. If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.

(d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated.

[Previous Document in Book] [Next Document in Book]