VERIFICATION

HERBERT J. NEVYAS, M.D. hereby states that I am president of Nevyas Eye Associates, P.C.; I am authorized to make this verification on behalf of defendant; I verify that the statements made in the foregoing discovery responses are true and correct to the best of my knowledge, information and belief; I understand these statements made are subject to the penalties of 18 Pa.C.S. §4904 relating to unsworn falsification to authorities.

July 29, 2002

HERBERT J. NEVYAS, M.D.

Declaration of Jo E. Janson Wills

I, Jo E. Janson Wills, make this declaration to place this matter of record, subject to the penalties of 18 Pa.C.S.A. Sec. 4904 relating to unsworn falsification to public authorities. I declare that:

1. My address is 40 Sycamore Drive, Burlington, NJ 08016
2. I was a plaintiff in the Wills v. Nevyas lawsuit, Philadelphia Court of Common Pleas July 2001 term, number 2866.
3. Dr. Nevyas testified that he did not report his patient Keith Wills to the Food and Drug Administration (FDA) as either an adverse event or complication following LASIK eye surgery using the Nevyas Excimer Laser under an Investigational Device Exemption (IDE) from the FDA. FDA staff has told me that all patients must be included in the reports to the FDA.
4. I filed a complaint with the Food and Drug Administration (FDA) against Herbert Nevyas, M.D. and Nevyas Eye Associates, and also requested information about Dr. Nevyas under the Freedom of Information Act.
5. The attached August 5, 2004 letter from Matthew Tarosky, Pharm. D., CDR, U.S. Public Health Service is a true and faithful copy of an e-mail letter I received in response.

Date: August 20, 2004

Jo E. Janson Wills

-----Original Message-----
From: Tarosky, Matthew [mailto:MJT@CDRH.FDA.GOV]
Sent: Thursday, August 05, 2004 10:55 AM
To: 'Jo Wills'
Subject: RE: FDA Letter

Hello Ms. Wills,

Thank you for your message. The office in which I work, the Division of Bioresearch Monitoring, treats information like that provided by you as serious and conducts an evaluation of all reports of research misconduct. The information that you provided to me was assigned to an office colleague. I believe she may have sent you a response. The investigation of Dr. Nevyas included two inspections over the past several years. If you would like a copy of those inspection reports and related correspondence, please contact FDA's Freedom of Information Office. You can also obtain information through the web at: http://www.fda.gov/opacom/backgrounders/foiahand.html The investigation of Dr. Nevyas is closed at this time.

It is my understanding that your adverse event report was reviewed from a public safety perspective along with all of the other adverse event reports received for the same medical device which ultimately resulted in the study being stopped. Thank you very much for the information that you provided. It was very helpful in FDA's evaluation of the risks and complications associated with the use of this medical device. Unfortunately, I can not give you any further details about the study. I do know, though, that FDA did introduce on their web-site awhile back a substantial amount of information about risks and complications regarding the use of lasers for corrective eye surgery. Hopefully, further complications will be minimalized.

Sincerely,

Matthew Tarosky, Pharm.D.
CDR, U.S. Public Health Service
HHS/FDA/CDRH/OC/DBM
(301) 594-4718 ext. 130

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1999

Herbert J. Nevyas, M.D.
Nevyas Eye Associates
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, PA 19004

Re: G970088/S15
Sullivan Excimer Laser System (Nevyas Model)
Indications for Use: LASIK (Laser-Assisted In Situ Keratomileusis) to correct myopia of -0.5 to -15 Diopters (D) with up to -7 D of astigmatism for protocol NEV-97-001 Myopia; and, LASIK retreatment to correct myopia and myopic astigmatism of eyes treated with this laser prior to IDE approval
Dated: January 5, 1999
Received: January 6, 1999
HCFA Category: A-2
Next Annual Report Due: August 7, 1999

Dear Dr. Nevyas:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application providing validation data for the contrast sensitivity study. You have corrected the deficiency cited in our September 24, 1998 conditional approval letter. Your application is approved, and you may continue your investigation at the institution enrolled in your investigation where you have obtained institutional review board (IRB) approval. Your investigation is limited to one institution and 1015 subjects (2030 eyes): 990 subjects (1980 eyes) for myopia (- 0.5 to -15 D with up to -7 D astigmatism); and, 25 subjects (50 eyes) for enhancements of subjects treated prior to IDE approval (-0.5 to -15 D myopia with up to -7 D astigmatism).

Please be aware of the following:

In Table 1-1, the data appear to be quite scattered, with some subjects actually increasing in sensitivity during glare (e.g., see BC & CB at 3 cycles per degree (CPD)), while others are severely compromised (see ZM). In order to reduce variability in the data in the contrast sensitivity study, the person administering the test should have experience in this test and the subjects should be well trained prior to testing.

We continue to be concerned that your ablation is likely to have multifocal properties, which means that some light will be out of focus even at the best focal plane. It is possible that your proposed mesopic contrast sensitivity study will help resolve some of these concerns. Also, any claims you may wish to assert regarding advantages of multifocality may not be supported by your change in accommodation study.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

Nancy C Broadon for

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration Rm. 900 US Customhouse, 2nd and Chestnut Sts. Phila. PA 19106 (215) 597-4390	4/19,20, 23-30, 30, 5/1-4,7, 10/2001
	FEI NUMBER 2531320

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Herbert J. Nevyas MD

FIRM NAME	STREET ADDRESS
Medical Director	2 Bala Plaza, 333 City Ave
CITY, STATE AND ZIP CODE Bala Cynwyd PA 19004	TYPE OF ESTABLISHMENT INSPECTED Sponsor/Clinical Investigator

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The following observations refer to the Investigational Device Exemption (Protocol # NEV-97-001) for the indicated study, "LASIK (Laser Intrastromal Keratomileusis) with an Excimer Laser in the Surgical Treatment of Refractive errors: Myopia with and without Astigmatism"

1. There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements] prior to implementation.

   For example, the FDA granted your firm an increase in the number of subjects you could treat with your investigational device on Jan. 20, 1999. IRB Annual Review dated 7/29/00 does not indicate the IRB knew about population increase. The IRB did not approve the population increase until August 28, 2000, 20 months later

2. The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.

3. There was a lapse of IRB approval for the protocol: NEV-97-001 from 8/3/2000 until 8/29/2000 according to IRB lapse notices and the IRB annual re-approval letter.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Ronald Stokes	Ronald Stokes	May 10, 2001

OCULAR SURGERY NEWS 2/15/2001

Industry news in brief

FDA OKs corneal disease study for Intacs

SCOTTSDALE, Ariz. — Clinical Research and Statistics (CRS), a physician research group based here, and KeraVision Inc. (NASDAQ: KERA) announced approval to perform a study that will initially involve Intacs implantation in 20 keratoconus patients at four U.S. centers, with possibly more patients and centers to be added subject to Food and Drug Administration (FDA) review and approval of initial clinical results.

Under the FDA's conditional approval of an investigational device exemption, CRS surgeons will be able to test whether the prescription inserts can improve patients' vision by strengthening and reshaping corneas that have been damaged by keratoconus.

The CRS study may pave the way for Intacs prescription inserts to be used in therapeutic applications, in addition to the refractive applications previously approved by the FDA.

Physician-sponsored clinical studies of Intacs inserts for keratoconus have been underway in Europe since 1997. Early clinical results have been encouraging, although limited and preliminary. The company plans to apply this year for formal CE mark approval.

The keratoconus study is the first of three studies that the CRS physician group wants to conduct for

Intacs. The group plans to seek FDA approval to use Intacs to treat LASIK patients. Potential LASIK-related applications include treating people with post-LASIK complications such as corneal thinning, undercorrection and visual regression. Also included in a second study would be people with severe myopia who might be treated with a combination of LASIK and Intacs to limit surgical ablation of the cornea. Subject to FDA approval, a proposed third study would explore the use of Intacs in treating glare, halos, starbursts, decentered laser ablations and other LASIK complications.

The initial keratoconus feasibility study will be conducted at four CRS-affiliated clinical sites. These include the Eye and Ear Institute at the University of Pittsburgh; Jules Stein Eye Institute at the University of California-Los Angeles; Nevyas Eye Associates/Delaware Valley Laser Surgery Institute, Bala Cynwyd, Pa.; and Lasersight Eyecare Medical Group Inc., Santa Barbara, Calif.