K014044

Notal Vision Inc.
5 Droyanov St. Tel-Aviv 63143, ISRAEL. Tel: 972-3-6293763 Fax: 972-3-6293764

MAR 4 2002

510(k) Summary Statement

Submitter:	Company Name:	**Notal Vision**, Inc.
	Address:	5 Droyanov Street Tel Aviv, 63143 Israel
	Contact Person:	Dr. Zeev Even Chen
	Phone:	(972) 3 6293763 Ext. 103
	Fax:	(972) 3 6293764
	Registration :	Pending

Manufacturer Information:

Company Name:	Notal Vision, Inc.
Address:	5 Droyanov Street Tel Aviv, 63143 Israel
Contact Person:	Dr. Zeev Even Chen
Phone:	(972) 3 6293763 Ext. 103

Registration Number: Pending

Official Correspondent:		Richard E. Lippman, O.D., F.A.A.O.
	Address:	C.L. McIntosh, Inc. 12300 Twinbrook Parkway Suite 230 Rockville, Maryland 20852
	Phone :	301-770-9590
	Fax:	301-770-9584

DEVICE IDENTIFICATION:

Trade Name:	Macular Computerized Psychophysical Test (MCPT)
Common Name:	Amsler Grid
Classification Name:	Amsler Grid

CLASSIFICATION
Name and Reference: 21 CFR 886.1330 Amsler Grid

REGULATORY CLASS	Class I
COMMON NAME:	Amsler Grid
ESTABLISHMENT REGISTRATION:	Pending

INDICATION for USE:

The Notal Vision Macular Computerized Psychophysical Test (MCPT) is indicated for the early detection of central and paracentral irregularities (vision abnormalities) in the visual field, most commonly associated with macular degeneration.

SUBSTANTIALLY EQUIVALENT TO:

The Notal Vision Macular Computerized Psychophysical Test is substantially equivalent to an Amsler Grid, a Class I Exempt medical device (21 CFR 886.1330) that is a chart with grids that is held at 30 centimeters distance from the patient and intended to rapidly detect central and paracentral irregularities in the visual field.

DEVICE DESCRIPTION:

The device is a computerized interactive software device that provides the user with a series of images oriented in vertical and horizontal planes on a imaging screen that is designed to identify irregularities in the central and paracentral macular field of the human visual system. The device analyzes the image presentation in the process of identifying visual field abnormalities and stores the analysis in a computer server. The device is housed in a PC computer.

CLINICAL INVESTIGATION

A prospective single blinded randomized clinical investigation was conducted at multiple investigational sites to evaluate the presence of central and paracentral visual field defects in the diagnosis of macular degeneration. The test device was the interactive software driven Macular Computerized Psychophysical Test (MCPT). The Amsler Grid chart was used as a comparison tool in two separate sets of subjects. Test subjects were those individuals with defined age-related macular degeneration (AMD) at different stages, and the control subjects were those with normal healthy eyes. Only one eye was tested in either the test group or the control group.

The primary objective of the study was to evaluate the ability of each technique to distinguish between patients with AMD at different stages and healthy controls without retinal abnormality.

The statistical tests, which was used for analyzing the results of this study, include comparative analysis to demonstrate the hypothesis that the MCPT is equal to or better than the Amsler grid in the detection of AMD-related retinal abnormalities, i.e., to

reject the null hypothesis which states: "The Amsler grid is better then the MCPT in detecting abnormalities in the macular area".

CLINICAL OUTCOMES AND CONCLUSIONS

Efficacy:

The MCPT indicated the presence of AMD significantly more often than the Amsler grid. The overall sensitivity of MCPT was 68.4%, compared with 25.6% of the Amsler grid. This difference is statistically significant. However, MCPT was also inclined to diagnose more Category 1 subjects (healthy subjects-false positives) as having AMD. The specificity of MCPT was 81.8%, compared to 100% for the Amsler grid.

MCPT and Amsler Grid Results per Category

	MCPT				Amsler Grid				
Category	-	+	Sens	Spec	-	+	Sens	Spec	P-Value[1]
1	27	6		0.818	33	0		1.0	0.0312500
2	30	21	0.412		47	4	0.078		0.0000763
3	6	14	0.70		16	4	0.20		0.0019531
4	1	26	0.963		15	12	0.444		0.0001221
5	0	19	1.0		9	10	0.526		0.0039063
TOTAL[2]	**37**	**80**	**0.684**		**87**	**30**	**0.256**		**0.0000001**

+ = Positive results; - = Negative results; Sens. = Sensitivity' Spec. = Specificity
[1] Calculated according to mcNemar Test for two related dichotomous variables.
[2] Categories 2 to 5.

The MCPT sensitivity analysis was calculated as follows:
Sensitivity = (21+14 +26 + 19)/[(21 +14 +26 +19) + 30 +6 +1 +0)] = 0.684
Specificity = 27/(27 +6) = 0.818

The Amsler Grid sensitivity analysis was calculated as follows:
Sensitivity = (4 +4 +12 + 10)/[(4 +4 +12 +10) + (47 +16 +15 +9)] = 0.256
Specificity = 33/(33) = 1

Safety:

No adverse events were observed or reported by the subjects throughout the study. It is concluded that both the MCPT and the Amsler grid are safe.

LABELING

The Notal Vision Macular Computerized Psychophysical Test (MCPT) is provided with a User Manual for the Practitioner. The information is available from the company:

Notal Vision, Inc.
5 Droyanov Street
Tel Aviv 63143, Israel
(972) 3 6293763

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

Notal Vision, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
C.L. McIntosh, Inc.
12300 Twinbrook Parkway Suite 230
Rockville, Maryland 20852

Re: K014044
Trade Name: Macular Computerized Psychophysical Test (MCPT)
Regulation Number: CFR 886.1330
Regulation Name: Amsler Grid
Regulatory Class: Class I
Product Code: HOQ
Dated: December 1, 2001
Received: December 7, 2001

Dear Dr. Lippman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

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

Copy

Indications Statement

510(k) Number (if known) K014044

Device Name: The Notal Vision Macular Computerized Psychophysical Test (MCPT)

Indications for Use:

The Notal Vision Macular Computerized Psychophysical Test (MCPT) is indicated for the early detection of central and paracentral irregularities (visual abnormalities) in the visual field, most commonly associated with macular degeneration.

Additional Claims:

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Presription Use ✓ OR Over -The-Counter Use _____

(Oprtional Format 1-2-96)

Denis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K014044