DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2007

Golden Vision, Inc.
Mr. Andres R. Quiroz, President
7436 S.W. 117th Ave, Suite 103
Miami, FL 33183

Re: K981432
Trade/Device Name: Haag-Streit Goldmann Manual Tonometer
Regulation Number: 886.1930
Regulation Name: Tonometer and accessories
Regulatory Class: II
Product Code: HKY
Dated: October 9, 1998
Received: October 15, 1998

Dear Mr. Quiroz:

This letter corrects our substantially equivalent letter of January 12, 1999.

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 (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 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 continue 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Gwendolyn Burns PhD

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 4


# GOLDEN VISION, INC.

7436 S.W. 117th AVE., SUITE 103
MIAMI, FLORIDA 33183
PHONE (305) 270-0877
FAX (305) 270-8373


ATTACH. 4

510(k) 981432

DEVICE NAME: GOLDMAN MANUAL TONOMETER

INDICTIONS FOR USE: THE GOLDMAN MANUAL TONOMETER IS AN APPLIANCE THAT SERVES TO MEASURE INTRAOCULAR PRESSURE, ACCORDING TO THE GOLDMAN METHOD. THE MEASURING OF THE PRESSURE REQUIRES TO MAINTAIN A UNIFORM APPLANATION OF THE SURFACE OF THE CORNEA.

IT IS SPECIALLY INDICATED IN GLAUCOMA DISEASE.

M K B Nicholas
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981432

Prescription Use M K B Nicholas
(Per 21 CFR 801.109)