



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Eyedetec Medical, Inc.
c/o Mr. Alan Curtis
Regulatory Consultant
3617 Scott Street
San Francisco, CA 94123

DEC 20 2011

Re: K113367

Trade Name: EyeGiene® Insta-Warmth System

Indications for Use: The EyeGiene Insta-Warmth System is a warm disposable pack for the application of localized heat therapy in cases of chronic inflammatory and cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye, and chalazia. The EyeGiene Insta-Warmth System also may relieve accommodative fatigue and may help recover baseline visual acuity levels after prolonged work on visual display terminals.

Regulation Number: 21 CFR 890.5710

Regulation Name: Hot or Cold Disposable Pack

Regulatory Class: Class I Exempt

Product Code: IMD

Dated: November 11, 2011

Received: November 15, 2011

Dear Mr. Curtis:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

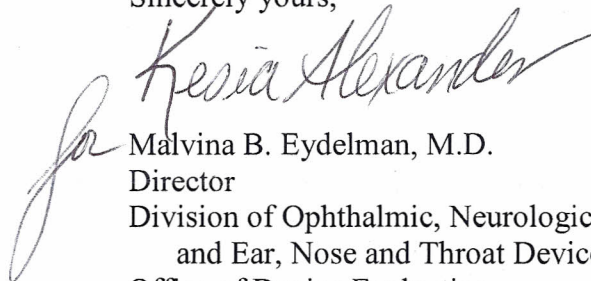
The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR), 21 CFR Section 890.5710. We suggest that you review this regulation since it may grant other exemptions from certain general controls of the Act. Your device classification regulation name, regulatory class, and product code are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug

Administration. We suggest, however, that you review 21 CFR Section 890.9 to determine whether or not your new device (s) meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact Marc Robboy, O.D. at (301) 796- 5620 or the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 796-7100, or at its Internet address “<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ucm142656.htm>”.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Malvina B. Eydelman". The signature is written in dark ink and is positioned to the left of the typed name.

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

Enclosure

K113367

Eyedetec Medical Inc.

EyeGiene Insta-Warmth System 510(k)
Premarket Notification

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113367

Device Name: EyeGiene Insta-Warmth System

Indications for Use:

The EyeGiene Insta-Warmth System is a warm disposable pack for the application of localized heat therapy in cases of chronic inflammatory and cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye, and chalazia.

The EyeGiene Insta-Warmth System also may relieve accommodative fatigue and may help recover baseline visual acuity levels after prolonged work on visual display terminals.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Marc Robboy

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113367