[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2005]
[CITE: 21CFR886.1700]



TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER H--MEDICAL DEVICES

PART 886 -- OPHTHALMIC DEVICES

Subpart B--Diagnostic Devices

## Sec. 886.1700 Pupillometer.

(a) *Identification.* A pupillometer is an AC-powered or manual device intended to measure by reflected light the width or diameter of the pupil of the eye.

(b) *Classification.* Class I (general controls). The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 886.9. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

[55 FR 48442, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994; 66 FR 38812, July 25, 2001]

# Device Listing Database

| | |
|---|---|
| **Proprietary Device Name:** | EYECHECK |
| **Common/Generic Device Name:** | PUPILLOMETER |
| **Classification Name:** | PUPILLOMETER, AC-POWERED |
| **Product Code:** | HLG |
| **Device Class:** | 1 |
| **Regulation Number:** | 886.1700 |
| **Medical Specialty**: | Ophthalmic |
| **Owner/Operator:** | INDIGO MICRO TECHNOLOGIES, INC. |
| **Owner/Operator Number:** | 9076945 |
| **Registered Establishment Name:** | INDIGO MICRO TECHNOLOGIES, INC. |
| **Establishment Registration Number:** | 1064491 |
| **Date of Listing:** | 03/09/00 |
| **Listing Status:** | Active |
| **Establishment Operations:** | Manufacturer, Specification Developer |

## Product Classification Database

| | |
|---|---|
| **Device** | pupillometer, ac-powered |
| **Regulation Description** | Pupillometer. |
| **Regulation Medical Specialty** | Ophthalmic |
| **Review Panel** | Ophthalmic |
| **Product Code** | HLG |
| **Submission Type** | 510(k) Exempt |
| **Regulation Number** | 886.1700 |
| **Device Class** | 1 |
| **GMP Exempt?** | No |

**Note:** FDA has exempted almost all class I devices (with the exception of Reserved Devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR xxx.9, where xxx refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, these manufacturers are required to register their establishment by submitting Form FDA 2891, "Registration of Device Establishment," and list the generic category or classification name of the device by submitting Form FDA 2892, "Device Listing."

| | |
|---|---|
| **Third Party Review** | Not Third Party Eligible |

**MCJ, Inc.**
**6019 Fincham Drive**
**Rockford, Illinois 61108**
**Website**: www.mcjeyecheck.com

**Phone: 815.966.0196**
**Fax: 815.966.0187**

GSA Contract Holder GS-07F-6026P

DOD EMALL

April 2006

Ref: Eye Safety

I wanted to inform and provide to you that the EyeCheck™ uses a very low-power Light Emitting Diode (LED) and ***NOT*** a Laser Diode.

There are many regulations on eye safety and maximum exposure levels of Lasers by different international standards groups. There are two prime safety standards for the rating of products with LED emissions. The IEC 60825-1 Edition 1 (1998-01) (Safety of Laser Products Part 1. Equipment classification, requirements and user's guide) and ANSI Z136.1 (American National Standard for Safe Use of Optical Fiber Communication Systems Utilizing Laser Diode and LED Sources).

The output optical power from the EyeCheck is measured at 0.89 micro-Watts (.00000089 Watts, or 0.89E-6 W) with a center wavelength in the near-IR just outside of the visible spectrum. This output optical power is collimated in a ~1.8-mm diameter beam. The resulting Optical Power Density is 35 micro-Watts/cm^2 (35E-6 W/cm^2). This will be needed in a bit to compare with safe limits.

For the equivalent laser diode (deemed more dangerous than LEDs w.r.t. eye safety*), the maximum permissible exposure (as defined by the ANSI standard listed above) for a 10 second exposure is 1.01E-03 W/cm^2. Even if you had a case where a person held open their eyes for 100 seconds, the maximum permissible exposure is 5.69E-04 W/cm^2. For this extreme case, the EyeCheck are still a factor of 16 times below the limit.

**To summarize, "Laser light is far more dangerous to the eyes than LED light of the same power. This is because the eye is able to accommodate and concentrate laser light to a very small retinal spot several wavelengths in diameter resulting in a high power density. In contrast, LED light, being from an extended source, cannot be efficiently focused down to much less than the source area, typically half a millimeter in diameter. Consequently, the potential retinal power density from a LED is over a thousand times less than that from a laser of the same power"*

I trust this should satisfy any questions form government or industry that should come up regarding the safety of the EyeCheck® Pupillometer.

Sincerely,

*John P. Dal Santo*

John P. Dal Santo, FACBS

CEO, MCJ Inc.