between 9 a.m. and 4 p.m., Monday through Friday.


List of Subjects in 21 CFR Part 886

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

1. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360k, 371.

2. Section 886.5200 is added to subpart F to read as follows:

§ 886.5200 Eyelid thermal pulsation system.

(a) Identification. An eyelid thermal pulsation system is an electrically-powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is used in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lid deficiency dry eye. The system consists of a component that is inserted around the eyelids and a component to control the application of heat and pressure to the eyelids.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing should validate electromagnetic compatibility (EMC) and safety of exposure to non-ionizing radiation;

(2) Design, description, and performance data should validate safeguards related to the temperature and pressure aspects of the device, including during fault conditions;

(3) Performance data should demonstrate the sterility of patient-contacting components and the shelf-life of these components;

(4) The device should be demonstrated to be biocompatible; and

(5) Performance data should demonstrate that any technological changes do not adversely effect safety and effectiveness.

Dated: August 12, 2011.

Nancy K. Stade,
Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–21179 Filed 8–18–11; 8:45 am]
BILLING CODE 4830–01–P