

## § 886.3100

device that is a light source intended to transmit light through tissues to aid examination of patients.

(b) *Classification.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered Class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48443, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994]

### Subpart C [Reserved]

### Subpart D—Prosthetic Devices

#### § 886.3100 Ophthalmic tantalum clip.

(a) *Identification.* An ophthalmic tantalum clip is a malleable metallic device intended to be implanted permanently or temporarily to bring together the edges of a wound to aid healing or prevent bleeding from small blood vessels in the eye.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 63 FR 59230, Nov. 3, 1998]

#### § 886.3130 Ophthalmic conformer.

(a) *Identification.* An ophthalmic conformer is a device usually made of molded plastic intended to be inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity and prevent closure or adhesions during the healing process following surgery.]

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 63 FR 59230, Nov. 3, 1998]

#### § 886.3200 Artificial eye.

(a) *Identification.* An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or the eviscerated eye-

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ball, for cosmetic purposes. The device is not intended to be implanted.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if the device is made from the same materials, has the same chemical composition, and uses the same manufacturing processes as currently legally marketed devices.

[61 FR 1124, Jan. 16, 1996]

#### § 886.3300 Absorbable implant (scleral buckling method).

(a) *Identification.* An absorbable implant (scleral buckling method) is a device intended to be implanted on the sclera to aid retinal reattachment.

(b) *Classification.* Class II.

#### § 886.3320 Eye sphere implant.

(a) *Identification.* An eye sphere implant is a device intended to be implanted in the eyeball to occupy space following the removal of the contents of the eyeball with the sclera left intact.

(b) *Classification.* Class II.

#### § 886.3340 Extraocular orbital implant.

(a) *Identification.* An extraocular orbital implant is a nonabsorbable device intended to be implanted during scleral surgery for buckling or building up the floor of the eye, usually in conjunction with retinal reattachment. Injectable substances are excluded.

(b) *Classification.* Class II.

#### § 886.3400 Keratoprosthesis.

(a) *Identification.* A keratoprosthesis is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye that is not a reasonable candidate for a corneal transplant.

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' "

(2) "510(k) Sterility Review Guidance of 2/12/90 (K90-1)," and

(3) "Guidance on 510(k) Submissions for Keratoprostheses."

[65 FR 17147, Mar. 31, 2000]