Food and Drug Administration, HHS

§ 886.1405 Ophthalmic trial lens set.
(a) Identification. An ophthalmic trial lens set is a device that is a set of lenses of various dioptic powers intended to be handheld or inserted in a trial frame for vision testing to determine refraction.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

§ 886.1410 Ophthalmic trial lens clip.
(a) Identification. An ophthalmic trial lens clip is a device intended to hold prisms, spheres, cylinders, or occluders on a trial frame or spectacles for vision testing.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

§ 886.1415 Ophthalmic trial lens frame.
(a) Identification. An ophthalmic trial lens frame is a mechanical device intended to hold trial lenses for vision testing.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 886.1420 Ophthalmic lens gauge.
(a) Identification. An ophthalmic lens gauge is a calibrated device intended to manually measure the curvature of a spectacle lens.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

§ 886.1425 Lens measuring instrument.
(a) Identification. A lens measuring instrument is an AC-powered device intended to measure the power of lenses, prisms, and their centers (e.g., lensometer).
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

§ 886.1430 Ophthalmic contact lens radius measuring device.
(a) Identification. An ophthalmic contact lens radius measuring device is an AC-powered device that is a microscope and dial gauge intended to measure the radius of a contact lens.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

§ 886.1435 Maxwell spot.
(a) Identification. A Maxwell spot is an AC-powered device that is a light source with a red and blue filter intended to test macular function.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.