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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. The submitter of this premarket notification is:

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2. The name of the device is the Rodenstock RO 5000 and RO 4000 Slitlamp. Its common name is the slitlamp and the classification name is the AC-powered slitlamp biomicroscope.

3. The RO 5000 device is substantially equivalent to the Haag-Streit brand slitlamp 900® BQ and the RO 4000 device is substantially equivalent to the Topcon brand slitlamp model SL-2ED.

4. The Rodenstock brand RO 5000 and RO 4000 slitlamps are instruments used for eye examination and the fitting of contact lenses. Each device consists of a microscope combined with a light source that can be narrowed into a slit for illumination of the eye. Each is available with accessories to measure characteristics of the eye and to document actual shapes. The device is powered by 6.3 to 12v AC and 50-60 Hz.

5. The device and accessories are indicated as a noninvasive aid in the examination and diagnosis of eye conditions and in the fitting of contact lenses. The indications are the same as those claimed for the predicate devices.

6. The technological characteristics are the same or similar to those found with the predicate devices where the eye is examined by projecting light onto it. Additionally, standard accessories are used for tonometry, examining the vitreous and fundus of the eye and contact lens fitting as those claimed for the predicate devices.

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