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510(K) SUMMARY[1] K962989

1. Name and Address

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2. Name of the Device

Tradename:	Amoils Epithelial Scrubber
Common name:	Corneal Epithelial Removal Device
Classification:	Powered corneal burr, Class I, 21 CFR §886.4070
Panel:	86 Ophthalmic
Procode:	HOG (Burr, Corneal)

3. Identification of Predicate Device(s)

The Pallikaris Automated Epithelial Removal Brush, K960261

4. Description of the Device

The Amoils Epithelial Scrubber ("epithelial scrubber") is a small, powered hand-held device to which is attached a single use brush with Tynex microfilaments. The microfilaments of the brush tip are encased in a retaining ring such that the diameter of the brush is 6.3mm. When being operated, the brush rotates in a circular fashion at approximately 1500 revolutions per minute.

5. Intended Use of the Device

The epithelial scrubber is intended for deepithelialization of the cornea in preparation for subsequent surgical procedures on the denuded cornea.

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[1] The FDA Checklist for summaries is attached.

6. Comparison of Technological Characteristics

Item to be Compared	Amoils Epithelial Scrubber	Pallikaris Epithelial Removal Brush, K960261
Intended Use	deepithelialization of the cornea in preparation for subsequent surgical procedures on the denuded cornea.	removal of the corneal epithelium prior to T-PRK® or PRK surgery
Tips, material	Tynex microfilament	soft plastic "pins" derived from a surgical hand brush
Tips, size	6.3mm	7mm
Tips, usage	single use	single use
Angle of Device Neck	90°	0°
Removal Time	3-5 seconds	2-5 seconds

The differences between the epithelial scrubber and the predicate device are minor and do not impact the safety and effectiveness of the device in any significant way. The difference in tip size does not affect safety and effectiveness, because the treatment zones can be increased with both devices by moving the device sideways to create a larger diameter. The 90° angle in the neck of the Amoils scrubber permits easier visualization of the epithelial removal by the surgeon, and the Tynex microfilaments of the Amoils device and the soft plastic "pins" of the Pallikaris brush are comparable.

7. Performance Data

The Amoils epithelial scrubber was used according to the instructions for use on eyes drawn from an eye bank. The eyes were then subjected to SEM and TEM photos, which confirmed that the epithelium was removed and the surface of the cornea was extremely smooth, with no damage to Bowman's layer. In addition, certain of the eye bank eyes were exposed to "worst case" treatments with the device, i.e., at twice the time and with excessive pressure. The photos from that part of the study again confirmed that the epithelium was removed and the surface of the cornea was extremely smooth, with no damage to Bowman's layer

The device was evaluated on 500 human eyes in a study conducted in South Africa. The procedure took from 3 to 5 seconds, confirming its equivalence to the reported speed of the Pallikaris brush (2 to 5 seconds). It was also found to promote quick healing, because the procedure does not remove the healthy epithelial rim from the 7 mm. zone to the limbus. This facilitates rapid central epithelium regrowth.

8. Safety and Effectiveness

Based on the data presented in this PMN, the Amoils epithelial scrubber is safe and effective:

- It permits rapid removal of the central 7 mm. corneal epithelium without damage to the harder Bowman's layer lying underneath.
- The Bowman's layer is not dried out by alcohol used in certain procedures and uneven dehydration of the stroma after mechanical scraping is eliminated.
- It is easy to visualize and manipulate through the microscope in the laser apparatus.
- No epithelial "tags" remain after the scrub.
- It promotes quick healing since it leaves intact healthy epithelial rim from the 7 mm. zone to the limbus, which facilitates rapid central epithelium regrowth.

In addition, a manual search in the Product SOS™[2] book found that no MDRs were reported.

9. Conclusions

The similarity in technological characteristics, coupled with the results of the work on both eye bank and human eyes, demonstrate the safety and efficacy of the Amoils Epithelial Scrubber and support the finding of substantial equivalence to the Pallikaris Epithelial Removal Brush, K960261.

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[2] Product SOS™, Medical Economics Data Production Company, Montvale, NJ 07645-1742.