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CONFIDENTIAL AND PROPRIETARY INFORMATION

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510(k) Summary per section 807.92(c)

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Name of Device: Accessory Illuminating Infusion Sleeve

Tradename of Device: Phacoilluminator™

Equivalence: The subject device is a predicate silicone infusion sleeve without opaque or tint additives.

Description of Device: Clear silicone sleeve that transmits light originating from fiber optic channels contained in the phacofragmentation handpiece.

Intended Use of Device: Provide illumination at surgical site.

Comparison with predicate devices: Construction material is identical with currently manufactured silicone infusion sleeve except that opaque additives are omitted to allow for light transmission.