

K960473



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510(k) Summary of Safety and Effectiveness

(in Accordance with SMDA of 1990)

Aesculap Power System Handpiece

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Product Name

Trade Name: Aesculap Power System Handpiece
Common Name: Powered Surgical Instrument Systems
Classification Name: Surgical Instrument Motors and Accessories (per 21 CFR Section 878.4820)

Predicate Device

The Power System Handpiece presented in this application is a modification to an existing device. Aesculap's modified Power System Handpiece is compared to its predecessor which is subject to #K770428. The modified Power System Handpiece is also compared to handpieces by Hall Surgical (#K864929) and Midas Rex (#K900388).

Device Description

The only modification to the device is in the length of the handpiece shaft which has increased from 75mm to 125mm. Aesculap's modified Power System Handpiece is a stainless steel device used for holding and delivering power to surgical accessories (i.e. burrs, drills.) The device has an overall length of 230 mm with a shaft angle of 21°. The handpiece holds drills and burrs with a shank diameter of 2.35 mm and a length of 180 mm. The device is connected to an electro-surgical motor unit via a power drive cable. The Power System Handpiece is compatible with Aesculap's Elan-E and Microtron power units. The internal gear ratio is 1:2, allowing the device to run at speeds of 0-36,000 rpm with the Elan-E and 0-54,000 rpm with the Microtron power unit.

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Intended Use

There has been no change in intended use for this modified device. The Power System Handpiece is intended for use for holding and delivering power to surgical accessories (i.e. burrs, drills).

Comparison of Technological Characteristics

Aesculap's Power System Handpiece is different from the predicate device from Aesculap only in the length of the shaft (increase from 75mm to 125mm). The shaft length is comparable to lengths offered by Hall Surgical and Midas Rex.

Performance Data

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device. However, the interface coupling on the Power System Handpiece meets the requirements of German DIN standard 13940 and International Standards Organization standard ISO 3964.

Substantial Equivalence

Aesculap believes that the Power System Handpiece presented in this submission is substantially equivalent in design, function, and intended use to the presented devices from Aesculap, Hall Surgical and Midas Rex.