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**stryker**<sup>®</sup>

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**Device Name:**

**Classification Names:** Instrument, Surgical, Orthopedic, DC Powered Motor and Accessories/Attachments:

21 CFR 878.4820, Class I

Bur, Surgical, General and Plastic Surgery

21 CFR 878.4820, Class I

Blade, Surgical, General and Plastic Surgery

21 CFR 878.4820, Class I

**Common/Usual Name:** Surgical Instrument Motors and Accessories/Attachments

**Proprietary Name:** Stryker Universal Drill Attachments and Accessories

**Device Sponsor:**

Stryker Corporation  
Instruments Division  
4100 E. Milham Avenue  
Kalamazoo, MI 49001  
Registration No: 1811755

**Regulatory Classification:** Class I

**Summary of Safety and Effectiveness:**

The Stryker Universal Drill Attachments and Accessories are intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone and other bone related tissue in a variety of surgical procedures including: ENT, orthopedic, maxillofacial, neuro, and plastics.

The Stryker Universal Drill Attachments are used in conjunction with the previously 510(k) cleared Stryker 75K Drill. The 75K drill motor is powered by DC electric current via the Total Performance System Console. The Extra Long Attachments are up to 400 mm in length. The Hudson Chuck reduces the speed of the 75K drill from 75,000 rpm to 700 - 1200 rpm. This chuck with Hudson fitting holds cranial perforators with a standard Hudson shank fitting.

The Stryker Universal Attachments are equivalent in intended use, safety, and effectiveness to existing powered instrument attachments marketed by companies such as Midas Rex and Codman.

The cutting accessories available will be provided sterile or nonsterile. The materials of construction, cutting action, and cutting surface configuration are equivalent to pre-1976 Medical Device Amendment cutting accessories distributed by Stryker as well as cutting accessories distributed by Midas Rex and Zimmer/Hall.

The Stryker Universal Drill Attachments and Accessories do not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Universal Drill Attachments and Accessories are substantially equivalent to these existing devices.



Diane Davis  
Regulatory Affairs Representative  
Stryker Instruments