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stryker®

INSTRUMENTS

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4100 East Milham Avenue
Kalamazoo, MI 49001-6197
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Device Name:

Classification Names: Surgical Instrument Motors and Accessories/Attachments:
21 CFR 878.4820, Class I and Class II

Common/Usual Name: Surgical instrument Motors and Accessories/Attachements

Proprietary Name: Stryker Command2 MicroElectric Surgical System

Device Sponsor:

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

Stryker Puerto Rico
Las Palmas Industrial Park
Highway 3, 130.2
Arroyo, Puerto Rico 00615
Registration No.: 2648666

Regulatory Classification: Class II

Summary of Safety and Effectiveness:

The Command2 MicroElectric System is 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, dental, orthopedic, maxiofacial, spinal, and plastics. It is also usable in the placement or cutting of screws, wires, pins, and other fixation devices.

The Stryker Command2 MicroElectric System, consisting of electrically powered surgical instruments, controls, power source, and other system accessories, is equivalent in intended use, safety, and effectiveness to powered instruments, controls, and associated accessories that were marketed by Stryker prior to the 1976 Medical Devices Amendment.

The cutting accessories available to be used with the Command2 MicroElectric System will be provided sterile. The materials of construction, cutting action, and cutting surface configuration are equivalent to devices distributed by Stryker prior to the 1976 Medical Devices Amendment. As proven in surgical procedures, these designs offer the required precision required for controlling the location and extent of the surgical contact.

The additional power source/console feature described in this submission is equivalent to existing power sources distributed by MicroAire. Intended use, function, and safety risks are all substantially equivalent. Safety warnings, malfunction troubleshooting, and operating duty cycles are listed in the Command2 MicroElectric System Operator's Manual. In addition, the Stryker Command2 MicroElectric System is designed to meet the following Standards: CSA 22.2 No. 601.1-M90, UL 2601-1 First Edition, IEC 601-1 with amendments, IEC 601-1-2, CISPR 11, IEC 1000-4-2, IEC 1000-4-3, IEC 1000-4-4, IEC 1000-4-5.

The Stryker Command2 MicroElectric System does not raise any new safety and efficacy concerns when compared to similar devices already being marketed. Therefore, the Stryker Command2 MicroElectric System is substantially equivalent to these existing devices.



Diane Davis
Regulatory Affairs Representative
Stryker Instruments