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stryker®
INSTRUMENTS
4100 East Milham Avenue
Kalamazoo, MI 49001-6197
(616) 323-7700 (800) 253-3210

Device Name:

Classification Names: Drill, Bone, Powered; 21 CFR 872.4120, Class II
Bur, Dental; 21CFR 872.3240, Class I
Controller, Foot, Handpiece and Cord; 21 CFR 872.4200, Class I

Common/Usual Name: Electrical Powered Surgical Instruments and Accessories/Attachments

Proprietary Name: Stryker Oral Max 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 Oral Max 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 but not limited to, dental and oral surgery. It is also usable in the placement of screws.

The Stryker Oral Max 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 Oral Max 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 power source/console described in this submission is equivalent to power sources distributed by Aeseptico. Intended use, function, and safety risks are all substantially equivalent. Safety warnings and operating duty cycles are listed in the Oral Max Operator's Manual. In addition, the Stryker Oral Max System is designed to meet the following Standards: CSA 22.2; UL 544.

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

Tammy Lounds
Supervisor, Regulatory Affairs
Stryker Instruments