

COMEG

Endoscopy

MAR 19 1997

K 970489
P192**SUMMARY OF SAFETY AND EFFECTIVENESS FOR GRASPING FORCEPS**

§807.92 (a)(1)

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§807.92 (a)(2)

Trade Name: COMEG Endoscopy Grasping Forceps

Common Name: Stone dislodger

Classification Name: Ureteral stone dislodger (21 CFR §876.4680)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Karl Storz Grasping forceps for removal of foreign bodies

§807.92 (a)(4)

Description of Device: The COMEG Endoscopy devices that we intend to market are foreign body Grasping Forceps. These forceps are composed of stainless steel. They have diameters of 7 and 9 French and lengths of 40 cm. Each model has an alligator jaw with a standard double action mechanism.

§807.92 (a)(5)

Intended Use: The intended use for the foreign body grasping forceps is in urological procedures to endoscopically remove, manipulate or grasp calculi (i.e. stones) and other foreign objects.

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§807.92 (a)(6)

Comparison of Technical Characteristics: The subject and predicate devices are similar in diameter, length, material, tip configuration, and tip action.