

K963499

Summary of Safety & Effectiveness Data for the Mirror Finish Bipolar Forceps Line

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1. **Contact Person**

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2. **Device Name**

Proprietary Name: Mirror Finish Bipolar Forceps
Common Name: Bipolar Forceps
Classification Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II by 21 CFR § 878.4400
Product Code: 79 GEI
Owner/ Operator # 9001269

3. **Device Classification**

Classification for bipolar forceps has been placed in Class II by 21 CFR § 878.4400

4. **Statement of Substantial Equivalence**

The safety and effectiveness of the JJPI Mirror Finish Bipolar Forceps is substantiated by similarity in its intended use and function to the JJPI Bipolar Forceps Line and the KIRWAN Non-Stick Bipolar Forceps. The functional testing and the basic mechanical properties exhibited by the JJPI non-stick forceps indicate that the JJPI proprietary coated tips are functionally equivalent to both the JJPI Bipolar Forceps Line and the KIRWAN Non-Stick Bipolar Forceps.

5. **Indications for Use**

These Mirror Finish Bipolar Forceps are indicated for use in any surgical procedure that requires tissue coagulation and/or cauterization to achieve hemostasis. They are indicated for use in:

1. general surgery,
2. neurosurgery,
3. urology, and nephrology.

6. Physical Description

The JJPI Bipolar Forceps Line is a modification of the bipolar forceps we currently have on the market. These forceps are made of either **stainless steel** or **titanium**. *The only difference* between our currently marketed line of bipolar forceps and the new line under consideration is the mirror finish proprietary coating that is applied to the tips.

Similarities and Differences Matrix

Features	JJPI Mirror Finish Bipolar Forceps	JJPI Bipolar Forceps Line	Kirwan Non-Stick Bipolar Forceps
DESIGN			
Tips highly polished	Yes	Yes	Yes
Non-Stick qualities	Yes	Yes	Yes
Tip size	0.25 mm - 2 mm	0.25 mm. - 2 mm	0.5 mm. - 2 mm
Forceps Shape	Bayonet and straight	Bayonet and straight	Bayonet and straight
Reusable	Yes	Yes	Yes
INTENDED USE			
Indicated for use in any surgical procedure which requires tissue coagulation and/or cauterization to achieve hemostasis.	Yes	Yes	Yes
They are indicated for use in: 1. general surgery, 2. neurosurgery, 3. urology, and nephrology.	Yes	Yes	Yes
MATERIALS			
Nickel	No	No	Yes
Stainless Steel, Titanium	Yes	Yes	No