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Bard Urological Division
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BARD

SECTION VI

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Submitter's Name: C. R. Bard, Inc.
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Date of Preparation: May 7, 1996

B. Device Name:

Trade Name: Bard V-Max²⁴ Roller Bar
Common / Usual Name: Electrode, Electrosurgical
Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

C. Predicate Device Name:

Trade Name: Circon ACMI VaporTrode™

D. Device Description:

The Bard V-Max²⁴ Roller Bar is a monopolar electrode designed to deliver radio frequency energy that is supplied by an electrosurgical generator cleared for medical use.

E. Intended Use:

The Bard V-Max²⁴ Roller Bar is indicated for ablation and coagulation of soft tissue and is intended for use with compatible resectoscopes.

F. Technological Characteristics Summary:

Table VI.1 provides a tabulated comparison of the technological characteristics of the Bard V-Max²⁴ Roller Bar versus the predicate device.

Table VI.1: Comparison Summary of Technological Characteristics

Comparison Topic	Bard V-Max²⁴ Roller Bar	Circon ACMI VaporTrode (Predicate Device)
Indications or Intended Use	(Indications) The Bard V-Max ²⁴ Roller Bar is indicated for ablation and coagulation of soft tissue and is intended for use with compatible resectoscopes.	(Intended Use) Used with compatible resectoscopes for vaporization and coagulation of tissue.
Resectoscope Compatibility	Examples of resectoscope compatibility include Circon ACMI (both USA and Classic series), Wolf, Storz and Olympus resectoscope.	Models available for Circon ACMI (both USA and Classic series) resectoscope.
Electrode Tip	Surface finished (smooth, grooved, etc.) metal roller.	Grooved metal roller.
Body Construction	Conductive wire jacketed with polymer insulator tubing and further jacketed with distal stainless steel outer shaft.	Conductive wire jacketed with polymer insulator tubing and further jacketed with distal stainless steel outer shaft.
Proximal Construction	Conductive contact compatible with specific resectoscopes.	Conductive contact compatible with specific resectoscopes.
Stabilizer	On applicable models.	On both models.