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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: June 25, 1996

B. Device Name:

Trade Name: Bard Coagulating Resector
Common / Usual Name: Electrode, Electrosurgical
Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

C. Predicate Device Name:

Trade Name: Microvasive® (Boston Scientific Corporation)
Wedge™ Electrosurgical Resection Device
Trade Name: CIRCON ACMI Right Angle Cutting Loop
Electrode

D. Device Description:

The Bard Coagulating Resector 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 Coagulating Resector is indicated for resection 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 Coagulating Resector versus the two predicate devices.

Table VI.1
Comparison Summary of Technological Characteristics

Comparison Topic	Bard Coagulating Resector	Microvase Wedge™ Electrosurgical Resection Device (Predicate Device)	CIRCON ACMI Right Angle Cutting Loop Electrode (Predicate Device)
Indications or Intended Use	(Indications) The Bard Coagulating Resector is indicated for resection and coagulation of soft tissue and is intended for use with compatible resectoscopes.	(Intended Use) Intended for cutting and coagulation during resection. To be used with compatible resectoscopes.	(Intended Use) Intended for cutting (resection). To be used with compatible resectoscopes.
Resectoscope Compatibility	Examples of resectoscope compatibility include CIRCON ACMI (both USA and Classic series), Wolf, Storz (both Single and Double stem), and Olympus resectoscope.	Models available for CIRCON ACMI USA series and Storz (Single stem) resectoscopes.	Fits compatible CIRCON ACMI resectoscopes.
Electrode Tip	Metal loop.	Metal loop.	Wire loop.
Body Construction	Conductive wire jacketed with black (polymer) insulator tubing and further jacketed with distal stainless steel outer shaft.	Conductive wire jacketed with polymer insulator tubing.	Conductive wire jacketed with polymer insulator tubing.
Proximal Construction	Conductive contact compatible with specific resectoscopes.	Conductive contact compatible with specific resectoscopes.	Conductive contact compatible with specific resectoscopes.
Stabilizer	On applicable models.	On all models.	On all models.