

K962077

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Bard Radiology Division  
13183 Harland Dr., N.E.  
Covington, GA 30209

**BARD**

**VI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

**Submitter Information:**

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Date of Preparation: May 13, 1996

**Device Name:**

Trade Name: Bard® Biopty-Cut® Biopsy Needle and  
Bard® Biopty-Cut® Biopsy Needle with  
Spacer

Common/Usual Name: Biopsy Needle

Classification Name: Gastroenterology-urology biopsy  
instrument, needle

**Predicate Device Name:**

Trade Name: Bard® Biopty-Cut® Biopsy Needle and  
Bard® Biopty-Cut® Biopsy Needle with  
Spacer

**Device Description:**

The Bard® Biopty-Cut® Biopsy Needle and Bard® Biopty-Cut® Needle with  
Spacer are single-use biopsy needles.

**Intended Use:**

The device is intended for use in obtaining biopsies from soft tissues  
such as liver, kidney, prostate, spleen, lymph nodes and various soft  
tissue tumors. It is not intended for use in bone.

**Technological Characteristics Summary:**

The Bard® Biopty-Cut® Biopsy Needle and Bard® Biopty-Cut® Needle with Spacer which are the subject of this Premarket Notification, have a modified sample notch. They are available in various gauges and lengths. The Bard® Biopty-Cut® Needle with Spacer is packaged with a computed topography spacer.

**Performance Data Summary:**

Testing confirms that the quality of the samples obtained with the modified notch needles are equivalent to the samples obtained from the standard sample notch needles.

**SECTION VI - TABLE 1**  
**Characteristics of Equivalent Devices**  
**Type of Instrument**

Characteristic	Bard® Biopty-Cut® Biopsy Needle 510(k) #K871390	CURRENT Bard® Biopty-Cut® Needle with and without Spacer 510(k) #K910720	PROPOSED Bard® Biopty-Cut® Needle with and without Spacer
<b>Indications for Use</b>	Percutaneous biopsy of the liver, kidney, prostate, spleen, lymph nodes and different tumors.	Obtaining core biopsy, of various organs and tissues. <sup>1</sup>	Obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissues. It is not intended for use in bone. <sup>1</sup>
<b>Needle Type</b>	Sterile, non-pyrogenic, 2-part cannula/stylet, stainless steel with plastic hubs.	Sterile, non-pyrogenic, 2-part cannula/stylet, stainless steel with plastic hubs.	Sterile, non-pyrogenic, 2-part cannula/stylet, stainless steel with plastic hubs.
<b>Reuse Status</b>	Disposable, not intended for re-use.	Disposable, not intended for re-use.	Disposable, not intended for re-use.
<b>Available Needle Diameters</b>	14,18, 20 gauge	12,14,16,18,20 gauge	12,14,16,18,20 gauge
<b>Available Needle Lengths</b>	16, 20cm	10, 16, 20cm (all gauges) 25, 30cm (16, 18 gauge)	10, 16, 20cm (all gauges) 25, 30cm (16, 18 gauge)
<b>Sample Notch Length</b>	17mm for 18 gauge 20mm for 14 gauge	17mm <sup>2</sup>	17mm for 12, 16, 18, 20 gauge 19mm for 14 gauge
<b>Configuration of Sample Notch Ends</b>	proximal = radius distal = radius	proximal = radius distal = radius	proximal = radius distal <sup>3</sup> = angled
<b>Centimeter Gradations on Cannula</b>	None	Optional	Optional
<b>Spacer Component</b>	None	Optional	Optional
<b>Etched Tip</b>	None	Optional	Optional

1. Indications for use were very general in #K910720. A subsequent 510(k) for biopsy needles, #K922939, included DFUs with more specific indications. These indications were used in the Biopty-Cut Biopsy needle line.
2. #K910720 noted that the sample notch length was 17mm for all needles. It should have noted that the notch length is 17 or 19mm, depending on gauge size.
3. distal = angled is the only change proposed. Test results and report presented in Appendix B of this submission show no significant difference could be detected between the samples collected by a needle with an angled distal sample notch and samples collected by a needle with a radius distal sample notch.

**SECTION VI - TABLE 1**  
**Characteristics of Equivalent Devices**  
**Type of Instrument**

Characteristic	CURRENT	PROPOSED
	Bard® Biopty-Cut® Biopsy Needle 510(k) #K871390	Bard® Biopty-Cut® Needle with and without Spacer 510(k) #K910720
<b>Number of Samples</b>	1 per fire	1 per fire
<b>Mechanics of Action</b>	Automatic, spring - driven	Automatic, spring - driven
<b>Mode of Action</b>	Single puncture and sample	Single puncture and sample

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