

K962702

**Section 10.0: 510(K) Summary**

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92( c ).

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**10.2 Date Summary Prepared**

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**10.3 Trade Name**

Spacemaker® Serial Surgical Balloon Dissector, Class II

Spacemaker® Serial Surgical Balloon Dissector with Cannula, Class II

Spacemaker® Serial Surgical Balloon Dissector with Visualization, Class II

Spacemaker® Serial Surgical Balloon Dissector with Visualization and Cannula, Class II

**10.4 Common Name**

Surgical Balloon Dissector with or without Cannula

**10.5 Predicate devices**

K944418 Spacemaker® and Spacemaker® II Surgical Balloon Dissector and Cannula,  
Class II

K951878 Spacemaker® and Spacemaker® II Surgical Balloon Dissector with and  
without a Cannula, Class II

01/16/97

23 (page number from original submission)

## **10.6 Device Description**

The Spacemaker® Serial Surgical Balloon Dissector device is a disposable, handheld, manually manipulated surgical balloon dissection device. The device consists of a balloon, center rod, handle, and suction/fill assembly. The device can be supplied either with a solid center rod or with a hollow center rod. The hollow center rod allows for the insertion of an endoscopic visualization accessory, if desired. Both versions can be inflated and deflated multiple times during a procedure.

The device can be supplied with or without a cannula. The cannula provides access for operative and diagnostic instrumentation for the duration of the surgical procedure.

This submission seeks clearance for the Spacemaker® Serial Surgical Balloon Dissector to be supplied in four configurations as follows:

Spacemaker® Serial Surgical Balloon Dissector, Class II

Spacemaker® Serial Surgical Balloon Dissector with Cannula, Class II

Spacemaker® Serial Surgical Balloon Dissector with Visualization, Class II

Spacemaker® Serial Surgical Balloon Dissector with Visualization and Cannula, Class II

## **10.7 Intended Use**

The intended use of the Spacemaker® Serial Surgical Balloon Dissector is the same as the predicate devices (K944418, K951878). The intended use of the Spacemaker® Serial Surgical Balloon Dissector and the predicate devices is to dissect layers of connective tissue along natural planes of separation. The cannula portion of the device is intended to provide access for operative and diagnostic instruments for the duration of the operative procedure.

## 10.8 Comparison to Predicate Devices

Point of Comparison	Spacemaker® and Spacemaker® II Surgical Balloon Dissector and Cannula (K944418)	Spacemaker® and Spacemaker® II Dissector with and without Cannula (K951878)	Spacemaker® Serial Surgical Balloon Dissector
Intended Use	Dissect layers of connective tissue along natural planes of separation.	Dissect layers of connective tissue along natural planes of separation.	Dissect layers of connective tissue along natural planes of separation.
Indications	Any area of the body where it is necessary to separate the layers of connective tissue for surgical access.	Any area of the body where it is necessary to separate the layers of connective tissue for surgical access.	Any area of the body where it is necessary to separate the layers of connective tissue for surgical access.
<i>Examples where surgical dissection of natural tissue planes can provide surgical access:</i>	General, laparoscopic, and endoscopic surgery	General, laparoscopic, endoscopic, plastic and reconstructive, including aesthetic surgery	General, laparoscopic, endoscopic, plastic and reconstructive, including aesthetic surgery and vascular use for the exposure of superficial veins of the upper and/or lower extremities; no arterial nor deep nor non-extremity structure would be targeted.
Supplied	Single patient use; Disposable	Single patient use; Disposable	Single patient use; Disposable
Balloon Inflations Per Procedure	Single	Single	Multiple
Principle of Operation	Handheld, manually manipulated surgical instrument	Handheld, manually manipulated surgical instrument	Handheld, manually manipulated surgical instrument
Balloon Volume Range	200-1500cc saline inflation	10-2500cc saline or air inflation	10-1000cc saline or air inflation
Packaging Configuration	Dissector with cannula	Dissector with cannula or Dissector without cannula	Dissector with cannula or Dissector without cannula
Balloon Shapes	Include kidney, clover, horseshoe, semi-round, and U-shaped profiles	Include kidney, clover, horseshoe, semi-round, and U-shaped profiles	Include kidney, clover, horseshoe, semi-round, U-shaped and elliptical profiles
Materials	Plastic, Stainless steel	Plastic, Stainless steel	Plastic, Stainless steel
Balloon Cover	Yes	Yes	No
Center Rod	Rigid or flexible	Rigid or flexible	Rigid or flexible
Endoscopic Visualization	No (Spacemaker®) Yes (Spacemaker® II)	No (Spacemaker®) Yes (Spacemaker® II)	Optional
Cannula Sizes (mm)	10/11 or 12/13	10/11, 12/13, or No Cannula	10/11, 12/13, or No Cannula

### **10.9 Testing in Support of Substantial Equivalence Determination**

Results of performance bench tests verify that the modifications do not affect the safety or efficacy of the Spacemaker® Serial Surgical Balloon Dissector compared to the predicate devices.

There is one material used in the Spacemaker® Serial Surgical Balloon Dissector (which was not used in the predicate devices). The remainder of the materials were used in the predicate devices. The material (a well known and commonly used silicone) meets the biocompatibility test requirements as defined in ANSI/AAMI 10993-1 (ISO 10993-1).