

**BOSS**  
**INSTRUMENTS, LTD.**

K980002

JUN 18 1998

*For the Art of Surgery™*

**Non-Confidential Summary of Safety and Effectiveness**

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December 29, 1997

Boss Instruments, Ltd.  
1310 Central Ct.  
Hermitage, TN 37076

Tel - (615) 885-2231  
Fax - (615) 885-2992

**Official Contact:** Burns Phillips, President  
**Proprietary or Trade Name:** Koala Vascular Clamps and Inserts  
**Common/Usual Name:** Vascular Clamps and Accessories  
**Classification Name:** Vascular clamps  
**Device:** Koala Vascular Clamps and Inserts  
**Predicate Devices:** Baxter V. Mueller - Fogarty Hydragrip Clamps and Inserts -  
K951413

**Device Description:**

The Boss Instrument Koala Vascular Clamps and inserts are reusable, ring-handled stainless steel instruments which have inserts which reduce trauma to the tissue being clamped.

**Indicated Use --** The Koala Vascular Clamps and Inserts are reusable, ring-handled stainless steel clamps for clamping delicate vessels during surgery. They are radiopaque, visualized under fluoroscopy. Designed for tip-first closure to prevent vessel roll-out. Applications include - pulmonary, gastrointestinal procedures, peripheral clamping, thoracic procedures such as occlusion of the aorta and vena cave, cross-clamping of the aorta and aortic aneurysms, etc.

**Environment of Use --** Hospital and operating room (OR)

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**Comparison to Predicate Devices:**

<b>Attribute</b>	<b>Koala Clamps and Inserts</b>	<b>Baxter -V. Mueller Fogarty K951413</b>
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**Use**

Indicated for clamping vessels and total occlusion	Yes	Yes
Used in pulmonary, gastrointestinal, peripheral clamping, thoracic procedures - occlusion of aorta, vena cava, cross clamping of aorta and aortic aneurysms, etc.	Yes	Yes
Intended to be reused	Yes	Yes

**Design**

Instruments manufactured by the same company	Yes	Yes
Various sizes and configurations offered	Yes	Yes
Incorporate inserts to reduce trauma available in 33, 61 and 86 mm sizes	Yes	Yes

**Packaging**

Inserts provided sterile in Tyvek pouches	Yes	Yes
Clamps provided clean, non-sterile	Yes	Yes

**Materials**

Clamps - Stainless Steel	Yes	Yes
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**Comparison to Predicate Devices:**

<b>Attribute</b>	<b>Koala Clamps and Inserts</b>	<b>Baxter -V. Mueller Fogarty K951413</b>
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**Materials**

Inserts - polyurethane	Yes	Yes
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**Performance Standards / Specifications**

Required under Section 514	None	None
Biocompatibility tests for Class VI for the insert material	Yes	Yes

**Differences between Other Legally Marketed Predicate Devices**

The clamps are manufactured and supplied by the same manufacturer. The inserts are manufactured by different companies, but the base material is exactly the same. Therefore there are no significant differences between the intended device and the predicate - Baxter - V. Mueller - Fogarty - Hydragrip Vascular Clamps and inserts approved under K951413.

JUN 18 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Burns Phillips  
President  
Boss Instruments, Ltd.  
1310 Central Ct.  
Hermitage, TN 37076

Re: K980002  
Trade Name: Koala Vascular Clamps and Inserts  
Regulatory Class: II  
Product Code: DXC  
Dated: April 17, 1998  
Received: April 21, 1998

Dear Mr. Phillips:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

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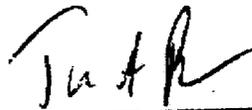
510(k) Number:     K 980002     (To be assigned)

Device Name: Koala Vascular Clamps and Inserts

Intended Use : The Koala Vascular Clamps and Inserts are reusable, ring-handled stainless steel clamps for clamping delicate vessels during surgery. They are radiopaque, visualized under fluoroscopy. Designed for tip-first closure to prevent vessel roll-out. Applications include - pulmonary, gastrointestinal procedures, peripheral clamping, thoracic procedures such as occlusion of the aorta and vena cave, cross-clamping of the aorta and aortic aneurysms, etc.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number     K980002    

Prescription Use            
(Per CFR 801.109)

or

Over-the-counter use