

K963388

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510 (k) SUMMARY

**I. ADMINISTRATIVE**

**Submitter:** Maxxim Medical, Inc , Argon Division  
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**Contact Person:** Eddie Monroe

**Date of Preparation:** August 26, 1996

**II. DEVICE NAME**

**Proprietary Name:** None

**Common Name:** Vessel Dilator

**Classification Name:** Vessel Dilator for percutaneous catheterization

**III. PREDICATE DEVICE**

Vessel Dilator component of Introducer for PTCA Guiding Catheters; K891022; Argon Medical.

**IV. DEVICE DESCRIPTION**

The Vessel Dilator is a device used over a guide wire to dilate the opening in a vessel in preparation of percutaneous entry of a catheter. The device may be used separately or in conjunction with a sheath introducer. The device consists of a plastic hub attached to a plastic cannula. The distal end of the cannula is thermally tapered to assist in dilation. The hub proximal end has a female luer lock configuration. An optional hub collar may be used to attach the dilator to an introducer. The device is available in sizes 4F through 15F and is supplied as a sterile, disposable single put up in sealed pouches, in non-sterile bulk quantities, or included as a component in catheter introducer kits, trays, or packs.

Biocompatibility of the device has been established by cytotoxicity, intracutaneous reactivity, sensitization, acute systemic toxicity and hemocompatibility tests. The device meets the requirements of the USP XXIII physico-chemical tests for plastics.

**V. INTENDED USE**

To enlarge the opening in a vessel in preparation of percutaneous entry of a catheter.

## **VI. COMPARISON TO PREDICATE DEVICE**

The Vessel Dilator is identical in design, function and intended use, and similar in composition, to the Vessel Dilator component of the Introducer for PTCA Guiding Catheters (Argon Medical; K891022). Results of performance testing indicate that the Vessel Dilator has improved tensile strength characteristics compared to the predicate device.

Accordingly, Maxxim Medical, Inc., Argon Division, concluded that the Vessel Dilator is safe and effective for its intended use and performs at least as well as the legally marketed predicate device.