

K963749

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Maxxim Medical, Inc., Argon Division
1445 Flat Creek Road
Athens, TX 75751
(903) 675-9321

Contact Person: Eddie Monroe

Date of Preparation: September 9, 1996

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II. DEVICE NAME

Proprietary Name: None

Common Name: High Pressure Injection Line

Classification Name: Cardiopulmonary bypass adaptor, stopcock, manifold or fitting

III. PREDICATE DEVICE

Advance High Pressure Lines; K911884; Advance Medical, Inc.

IV. DEVICE DESCRIPTION

The High Pressure Line is a device used as conduit tubing to deliver fluids from an electronic or manual injector and may also be used as connector tubing to provide a sterile fluid pathway between two devices. The device consists of plastic tubing with plastic luer lock connector hubs at each end. The luer lock connector hubs are a female/male combination or a female/rotating male combination. The device is available in lengths of 10 to 48 inches and 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

Conduit tubing to deliver fluids from an electronic or manual injector; connector tubing to provide a sterile fluid pathway between two devices.

VI. COMPARISON TO PREDICATE DEVICE

The High Pressure Injection Line is similar in design and composition, and identical in function and intended use to the High Pressure Line (Advance Medical; K911884). Results of simulated use tests, pull tests and static pressure tests indicate that the High Pressure Injection Line has performance characteristics equivalent to or better than those of the predicate device.

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