

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

ENDOSONICS Automatic Pull Back Device

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As an accessory, the Automatic Pull Back Device (PBD) does not affect the safe and effective use of the Endosonics Intravascular Ultrasonic Imaging System or the Endosonics Imaging catheters.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Automatic PBD is substantially equivalent in intended use and technologic characteristics to cardiovascular accessory devices: the CVIS Catheter Pull-Back Device and the Intertherapy Interpret Catheter Linear Translator. These predicate devices are legally commercially available.

COMPANY AND CONTACT PERSON

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DEVICE NAME

Automatic Pull Back Device

PREDICATE DEVICE(S)

1. CVIS Catheter Pull-Back Device
2. Intertherapy Interpret Catheter Linear Translator

DESCRIPTION OF DEVICE

The Automatic PBD is a battery powered device that is used in the catheterization laboratory during intravascular ultrasound assessment. The Automatic PBD has a nominal linear travel distance of approximately 12 cm and provides a uniform, slow pull back rate of the catheter's imaging element. The speed is selectable between 1 mm/sec or 0.5mm/sec. The Auto PBD has no direct or indirect patient contact. The device is constructed of materials common to the medical industry for both patient and non-patient contact devices and equipment.

STATEMENT OF INTENDED USE OF THE DEVICE

The Endosonics Automatic PBD is intended for use as a pull back accessory to the Endosonics Intravascular Ultrasound Imaging catheters. The Automatic Pull Back Device withdraws the imaging catheter from the vessel through the guide catheter.

INTENDED USE OF PREDICATE DEVICE

1. The Auto PBD is intended to be used as a pull-back accessory to CVIS intravascular ultrasound catheters. The Auto PBD pulls back the imaging element inside the catheter while the outer catheter body is stationary in the vessel.
2. The CVIS Catheter Pull-Back Device is intended to be used for uniform, slow velocity pull-back of intravascular ultrasound catheters.
2. The Intertherapy Interpret Catheter Linear Translator is intended to be used for uniform, slow velocity pull-back of intravascular ultrasound catheters.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

The Automatic PBD and the predicate devices have substantially equivalent technological characteristics (materials, design, specifications, and mode of operation). These accessory devices have no patient contact. The devices are designed so catheters will attach to a movable carriage. The Automatic PBD incorporates pull-back rates comparable to predicate devices.