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510(k) Summary
Simon Nitinol Filter™ System and
Simon Nitinol Filter/Straight Line™ System

Submitter's Name, Address, and Telephone Number

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Name of Device

Simon Nitinol Filter™ System and Simon Nitinol Filter/Straight Line™ System

Classification Name

Cardiovascular Intravascular Filter

Common Name

Vena Cava Filter System

Product Code

DTK

Predicate Devices

1. Simon Nitinol Filter/StraightLine™ System ("SNF/SL System") (K963014) and Simon Nitinol Filter™ System ("SNF System") (K963016).

Intended Use

The intended use of both Systems is to prevent embolisms from migrating to the pulmonary arteries.

Substantial Equivalence

The cleared SNF/SL and SNF Systems and the proposed models of the SNF/SL and SNF Systems are composed of a SN Filter and a delivery system. The SN Filter component is made of a nitinol alloy which has thermal shape memory properties. These properties allow the nitinol alloy wires to be formed into the shape of a filter. When cooled, the wires can be straightened to allow delivery through a small diameter catheter. The SN Filter resumes its original shape, a dome with six legs, when warmed to body temperature in the vena cava.

The SN Filters are delivered via the Seldinger technique, using a 7 French I.D. angiographic introducer sheath and a preliminary venacavogram. The sheath is introduced into the vein and positioned in the vena cava. When the sheath is positioned in the vena cava, the dilator is removed and the delivery system for the SN Filter is attached to the sheath. The SN Filter is then advanced through the sheath using the pusher wire until the SN Filter is at the tip of the sheath in the vena cava. The pusher wire has a stainless steel pusher cup or pad on the distal end of the pusher wire. The pusher wire is held in position while the sheath is withdrawn. This action releases the SN Filter into the vena cava; the SN Filter expands to its original shape which secures it against the vena cava. The sheath is then removed.

NMT intends to modify the gold radiopaque marker band from one which is deposited onto the introducer sheath to one which is mechanically swaged onto the introducer sheath.

The proposed models of SNF/SL and SNF Systems have the same intended use as both cleared systems. These devices are intended to prevent embolisms from migrating to the pulmonary arteries. They have equivalent principles of operation as they use a pusher wire to push the SN Filter through a sheath inserted into a vein in order to deliver the filter to the inferior vena cava. The minor technological difference between the proposed models of SNF/SL and SNF System and the cleared SNF/SL and SNF System, namely the method by which the gold radiopaque marker

band(s) are applied to the sheath, does not raise any new questions of safety or effectiveness. Thus, the proposed models of SNF/SL and SNF Systems are substantially equivalent to the cleared SNF/SL and SNF System respectively.