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510(k) Summary

Nitinol Medical Technologies, Inc.'s

Simon Nitinol Filter/Straight Line™ System

Submitter's Name, Address, and Telephone Number

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as Regulatory Counsel to Nitinol Medical Technologies, Inc.

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Name of Device

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/Straight Line™ System (K944353)
2. Simon Nitinol Filter™ System (K940489, K912144, and K894703)

Intended Use

The intended use of Nitinol Medical Technologies, Inc.'s ("NMT") Simon Nitinol Filter/Straight Line™ System ("SNF/SL System") is to prevent pulmonary embolisms from migrating to the pulmonary arteries.

Substantial Equivalence

The cleared SNF/SL System and the proposed models of the SNF/SL System 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 placed in saline, the wires become soft and can be straightened to allow delivery through a small diameter catheter. The SN Filter reassumes 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 ("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 The pusher wire is held in position while the sheath is withdrawn.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 make three types of modifications to the cleared SNF/SL System. First, NMT intends to market models of SNF/SL System with zero, one, and two gold, radiopaque marker bands. Second, NMT intends to expand the delivery methods of the cleared SNF/SL System to include antecubital delivery and to modify the device's delivery system to allow antecubital delivery. Third, NMT intends to expand the device's delivery methods to include subclavian delivery using the same delivery system as used for jugular delivery.

The proposed models of SNF/SL System have the same intended use as the cleared SNF/SL System and the SNF System. These devices are intended to prevent pulmonary embolisms from migrating to the pulmonary arteries. They have equivalent principles of operation as they deliver a pusher wire to push the SN

Filter through a sheath inserted into a vein to the inferior vena cava. The minor technological differences between the proposed models of SNF/SL System and the cleared SNF/SL System, namely the removal of one or both radiopaque marker bands from some models, the revision of device labeling to include antecubital and subclavian delivery of the devices, and the modifications in the length of the device's sheath and pusher wire to allow antecubital delivery, do not raise any new questions of safety or effectiveness. The minor technological differences between the proposed models of the SNF/SL System and the SNF System, namely the SNF System's circular plastic storage and deployment system to advance the pusher wire, also do not raise any new questions of safety or effectiveness. Thus, the proposed models of SNF/SL System are substantially equivalent to the cleared SNF/SL System.