K963876

NOV 18 1996

510(k) Summary

Nitinol Medical Technologies, Inc.'s

Simon Nitinol Filter™ System

Submitter's Name, Address, and Telephone Number

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as Regulatory Counsel to Nitinol Medical Technologies, Inc.

Date Prepared

August 2, 1996

Name of Device

Simon Nitinol Filter™ System

Classification Name

Cardiovascular Intravascular Filter

Common Name

Vena Cava Filter System

Product Code

DTK

Predicate Devices

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

Intended Use

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

Substantial Equivalence

The cleared SNF System and the proposed models of the SNF 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 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 The pusher wire is held in position while the sheath is withdrawn.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 make two types of modifications to the cleared SNF System. First, NMT intends to market models of the SNF System with zero, one, and two gold, radiopaque marker bands. Second, 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 System have the same intended use as the cleared SNF System and the SNF/SL 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 the SNF System and the

cleared SNF System, namely the addition of one or two radiopaque marker bands to some models and the revision of device labeling to include subclavian delivery of the device does not raise any new questions of safety or effectiveness. Thus, the proposed models of the SNF System are substantially equivalent to the cleared SNF System.