510(k) Summary

Date Prepared:	26 July 2017
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Device:

Trade Name:	Cook Celect® Platinum Vena Cava Filter Set for Femoral Vein Approach Cook Celect® Platinum Vena Cava Filter Set for Jugular Vein Approach Cook Celect® Platinum Vena Cava Filter Set for Femoral and Jugular Vein Approach
Common Name:	Inferior Vena Cava Filter
Review Panel:	Cardiovascular
Classification Name:	Intravascular Filter (21 CFR 870.3375, Product Code DTK)
Classification:	Class II

Indications for Use:

The Cook Celect Platinum Filter implant is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent PE where anticoagulant therapy has failed or is contraindicated.

The Cook Celect Platinum Filter implant may be retrieved if clinically indicated; please refer to the "Optional Filter Retrieval" section of this booklet for more information.

The product is intended for percutaneous placement via a femoral or jugular vein for filtration of inferior vena cava (IVC) blood to prevent PE.

Predicate Device:

The Cook Celect Platinum Vena Cava Filter Sets are substantially equivalent to the predicate devices:

- Cook Celect Platinum Vena Cava Filter Sets cleared under K121629 on 03 July 2012.

Comparison to Predicate Device:

It has been demonstrated that the subject Cook Celect Platinum Vena Cava Filter Sets are substantially equivalent to the predicate Cook Celect Platinum Vena Cava Filter Sets (K121629). No changes have been made to the Cook Celect Platinum Vena Cava Filter or its delivery systems; the Cook Celect Platinum Vena Cava Filter Sets are identical to the predicate devices in terms of intended use, principles of operation, design, materials of construction, manufacturing processes, sterilization process, and basic technological characteristics. The purpose of this submission is to update device labeling based on safety and performance information gathered from post-market experience and to align with current international and regulatory standards. In addition, the shelf life of the Cook Celect Platinum Vena Cava Filter Sets was extended to three years.

Device Description:

The Cook Celect Platinum Vena Cava Filter is an IVC filter intended for use in prevention of recurrent PE. The filter is intended for percutaneous placement via either the jugular vein or femoral vein for filtration of blood within the IVC. The Cook Celect Platinum Vena Cava Filter Set is available in a Femoral Set and a Jugular Set. Each set consists of a preloaded filter, a coaxial introducer system, a hydrophilic coated pre-dilator, and a three-way stopcock. The filter is introduced and placed via a 7 French coaxial introducer system with a Check-Flo® valve. The femoral filter introducer has a flexible tip. The introducer dilator has 8 sideports and two radiopaque markers 30 mm apart. The Cook Celect Platinum Vena Cava Filter Set is also available in a universal vein access version consisting of components for both femoral and jugular vein approaches. The Cook Celect Platinum Vena Cava Filter is constructed from a cobalt chromium alloy. Radiopaque markers constructed from a platinum tungsten alloy located on each primary leg enhance filter visibility on procedural imaging. The filter is approximately 49 mm long along its main axis when compressed to a diameter of 30 mm.

Performance Testing:

No changes to the design, manufacturing, sterilization, or principles of operation have been introduced with the subject devices. Three-year shelf life was supported by nonclinical aging testing, which included packaging testing and performance testing; all test results met the pre-determined acceptance criteria. Final clinical study data were provided; interim data have been provided to FDA under previous 510(k)s and a summary of the final data has previously been provided to FDA under an IDE.

Conclusion:

The Cook Celect Platinum Vena Cava Filter Sets are substantially equivalent to the predicate devices. No changes have been made to the filter implant or the delivery systems. The changes being made included updates to device labeling and an extension of the device shelf life.