Assignment 2

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RGA6370 – Advanced Regulatory Writing: Medical Device Submissions

Submitted to: Professor Angel Estrada

January 23, 2026.

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92.

Applicant Information
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Date Prepared: 23 January 2026

Device Name and Classification
Trade Name: VascuCage™ Inferior Vena Cava Filter
Common Name: Inferior vena cava filter
Classification Name: Inferior vena cava filter
Regulation Number: 21 CFR 870.3375
Product Code: DTK
Device Class: Class III

Predicate Device:

The VascuCage™ Inferior Vena Cava Filter claims substantial equivalence to the legally marketed Crux® Vena Cava Filter (VCF), manufactured by Volcano Corporation and cleared under Premarket Notification K150262.

Device Description:

The VascuCage™ Inferior Vena Cava Filter is an endovascular medical device intended to prevent pulmonary embolism through mechanical capture of thromboemboli within the inferior vena cava. The device consists of a self-expanding metallic filter structure designed to be placed percutaneously within the inferior vena cava. The filter is designed to maintain vena cava patency while promoting improved local hemodynamics through its structural configuration.

The VascuCage™ filter is delivered via a single-use, disposable catheter-based delivery system compatible with standard introducer sheaths and guidewires. The delivery system is designed for deployment via either femoral or jugular venous access using standard interventional techniques. The device may be implanted as a permanent or temporary filter and is designed to support optional retrieval when clinically indicated using commercially available retrieval tools. The scientific principles underlying the VascuCage™ device,

including mechanical clot capture and passive blood flow maintenance, are consistent with those used in currently marketed vena cava filters

Intended Use:

The VascuCage™ Inferior Vena Cava Filter is indicated for the prevention of pulmonary embolism by capturing thromboemboli migrating from the lower extremities to the lungs in adult patients who have contraindications to anticoagulation therapy or in whom anticoagulation therapy has failed. The device is intended for placement in the infrarenal or suprarenal inferior vena cava and may be implanted as a permanent or temporary device. The VascuCage™ may be deployed percutaneously via a femoral vein or jugular vein approach.

The intended use and indications for use of the VascuCage™ device are the same as those of the predicate Crux® Vena Cava Filter. Therefore, no differences in intended use exist that would affect the safety or effectiveness of the device when used as labeled.

Technological Characteristics Comparison
The VascuCage™ Inferior Vena Cava Filter and the Crux® Vena Cava Filter share similar technological characteristics with respect to design, materials, deployment method, and mode of action. Both devices are self-expanding vena cava filters intended to mechanically capture thromboemboli while maintaining inferior vena cava patency.

Characteristic	VascuCage™ IVC Filter	Crux® Vena Cava Filter
Intended function	Mechanical capture of thromboemboli	Mechanical capture of thromboemboli
Anatomical location	Inferior vena cava (infra- or suprarenal)	Inferior vena cava (primarily infrarenal)
Deployment method	Percutaneous catheter-based delivery	Percutaneous catheter-based delivery
Access route	Femoral or jugular vein	Femoral or jugular vein
Filter design	Self-expanding metallic filter	Self-expanding nitinol wireform filter
Implant duration	Permanent or temporary	Permanent or retrievable
Retrieval capability	Optional retrieval	Optional retrieval

Substantial Equivalence Rationale:

The VascuCage™ Inferior Vena Cava Filter has the same intended use and similar technological characteristics as the predicate Crux® Vena Cava Filter. Both devices utilize self-expanding metallic filter structures deployed percutaneously within the inferior vena cava to mechanically capture thromboemboli and reduce the risk of pulmonary embolism.

Any differences between the VascuCage™ device and the predicate device are limited to design refinements intended to optimize filter stability and local hemodynamics. These differences do not alter the fundamental scientific technology of the device and do not raise new or different questions of safety or effectiveness. As such, the VascuCage™ device is substantially equivalent to the predicate device within the meaning of section 513(i) of the Federal Food, Drug, and Cosmetic Act.

REFERENCES:

[1] U.S. Food and Drug Administration. (2023). *Premarket notification 510(k) program*. https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k

[2] U.S. Food and Drug Administration. (2023). *510(k) summary requirements (21 CFR §807.92)*. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/section-807.92

[3] U.S. Food and Drug Administration. (2023). *Classification of medical devices*. https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

[4] U.S. Food and Drug Administration. (2023). *Code of Federal Regulations, Title 21, Part 870—Cardiovascular devices*. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-870

[5] Volcano Corporation. (2016). *Crux® vena cava filter instructions for use*. Volcano Corporation.

[6] Volcano Corporation. (2015). *Crux® vena cava filter 510(k) summary (K150262)*. Volcano Corporation.