Assignment 1 (Part 2)

Submitted by: Aastha Dave

College of Professional Studies, Northeastern University

RGA6370 – Advanced Regulatory Writing: Medical Device Submissions

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Regulatory Strategy for the VascuCage™ Device

Vascular Concepts is developing the VascuCage™, a novel inferior vena cava (IVC) filter intended to prevent pulmonary embolism through mechanical capture of thromboemboli. The device is an implantable vascular filter designed for placement within the inferior vena cava and incorporates design features intended to improve local hemodynamics while maintaining venous patency. This document outlines the proposed regulatory strategy for the VascuCage™ device, including the proposed indications for use and the recommended U.S. regulatory pathway, in alignment with current regulatory requirements and market precedents.

Product Name
VascuCage™

Model Number
TBA

Design Status:

The VascuCage™ represents the introduction of a new medical device. It is a newly developed implantable IVC filter and does not represent a modification or change to an existing marketed product. The device is intended for use in adult patients at risk for pulmonary embolism and is designed to be deployed via established venous access techniques.

Proposed Indications for Use Statement:

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 is designed to improve local hemodynamics while maintaining venous blood flow.

The VascuCage™ is intended for either permanent or temporary implantation and may be deployed percutaneously via a jugular vein or femoral vein approach, or by surgical cutdown of the superficial epigastric vein.

Proposed Marketing Claims:

“The VascuCage™ Inferior Vena Cava Filter is designed to mechanically capture thromboemboli migrating from the lower extremities toward the pulmonary circulation while maintaining inferior vena cava patency.”

“The device is designed to promote improved local hemodynamics within the inferior vena cava through its structural configuration while preserving venous blood flow.”

“The VascuCage™ filter is intended for placement in either the infrarenal or suprarenal inferior vena cava in adult patients, based on clinical judgment and patient anatomy.”

“The device is compatible with both temporary and permanent implantation strategies and is designed to support optional retrieval when clinically indicated.”

“The VascuCage™ may be delivered percutaneously via jugular or femoral venous access or by surgical cutdown of the superficial epigastric vein using established interventional techniques.”

Similar Competitive (Equivalent) Product(s):

Competitive devices currently marketed or previously marketed in the United States include

1. the Volcano Crux™ Vena Cava Filter,
2. the Günther Tulip® Vena Cava Filter, and
3. the Celect™ Platinum Vena Cava Filter.

These devices establish regulatory and clinical precedent for IVC filters intended to prevent pulmonary embolism.

Proposed Target Market(s):

The initial target markets for the VascuCage™ device are the United States, the European Union, and Canada.

Proposed Product Release Dates (per country)

The anticipated product release dates for the United States, European Union, and Canada are to be determined and will be dependent on regulatory approval timelines in each jurisdiction.

Device Classifications:

In the United States, the VascuCage™ is classified as a Class III medical device.

In the European Union, the device is classified as Class III under Regulation (EU) 2017/745.

In Canada, the device is classified as a Class IV medical device under the Canadian Medical Devices Regulations.

Applicable Guidance Documents and Standards:

Development and regulatory submission activities for the VascuCage™ device will be guided by applicable FDA, Health Canada, and European Union regulations and standards. These include FDA Premarket Approval application guidance, FDA design control requirements, ISO 10993 for biological evaluation of medical devices, ISO 14971 for risk management, ISO 13485 for quality management systems, Regulation (EU) 2017/745 on medical devices, and Health Canada guidance on the risk-based classification system for medical devices.

Proposed Regulatory Pathway:

Based on the intended use, implantable nature, anatomical placement within the central circulatory system, and the associated risks to patients, the VascuCage™ device is considered a high-risk medical device.

In the United States, inferior vena cava filters are regulated as Class III devices for which general and special controls are insufficient to provide reasonable assurance of safety and effectiveness. Consequently, the appropriate regulatory submission type for the VascuCage™ device is a Premarket Approval (PMA) application in accordance with 21 CFR Part 814.

Although legacy IVC filters were previously cleared through the 510(k) pathway, current FDA expectations require comprehensive clinical evidence due to known risks such as device migration, fracture, perforation, and embolization.

Selection of the PMA pathway provides the most appropriate and compliant regulatory strategy for initial U.S. market entry and supports subsequent global regulatory approvals.

REFERENCES:

[1] U.S. Food and Drug Administration. (2023). Premarket approval (PMA). https://www.fda.gov

[2] U.S. Food and Drug Administration. (2023). Code of Federal Regulations, Title 21. https://www.ecfr.gov