

K233680 Celect Platinum Vena Cava Filter Set for Femoral Vein Approach (IGTCFS-65-1-FEM-CELECT-PT)

Jan 18, 2024
63 days to decisionK233680 · Product code: DTK · Cardiovascular
Source: <https://www.510kdatabase.net/k233680/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	Nov 16, 2023
Decision date	Jan 18, 2024
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Celect Platinum Vena Cava Filter Set for Jugular Vein Approach (IGTCFS-65-1-JUG-CELECT-PT); Celect Platinum Vena Cava Filter Set for Femoral and Jugular Vein Approach (IGTCFS-65-1-UNI-CELECT-PT); Günther Tulip Vena Cava Filter Set for Femoral Vein Approach (IGTCFS-65-1-FEM-TULIP); Günther Tulip Vena Cava Filter Set for Jugular Vein Approach (IGTCFS-65-1-JUG-TULIP); Günther Tulip Vena Cava Filter

APPLICANT

Company	William Cook Europe Aps
Location	Bjaeverskov, DK
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510(k) history	18 submissions · 18 cleared · 2007-2025

REGULATORY CONSULTANT

Consulting firm	Cook Medical
Contact	Jennifer Brown

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233680/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026