

**K201533 Avinent Biomimetic Coral and Ocean-Iceberg Sterilization Cassettes**Mar 1, 2021  
266 days to decisionK201533 · Product code: **KCT** · General Hospital  
Source: <https://www.510kdatabase.net/k201533/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Jun 8, 2020
Decision date	Mar 1, 2021
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avinent Implant System S.L.U.</b>
Location	Santpedor, ES
Contact	Anna Cortina
510(k) history	2 submissions · 2 cleared · 2020-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Blackwell Device Consulting</b>
Contact	Angela Blackwell

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201533/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026