

K112961 CLO-SURPLUS P.A.D.Oct 31, 2011
27 days to decisionK112961 · Product code: **QSY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k112961/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Oct 4, 2011
Decision date	Oct 31, 2011
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scion Cardio-Vascular, Inc.
Location	Miami, FL, US
Contact	CRAIG PAGAN
510(k) history	4 submissions · 4 cleared · 2004-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112961/> 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 June 18, 2026