

K831865 IONESCU-SHILEY LOW POROSITY COMPOSITEOct 19, 1983
131 days to decisionK831865 · Product code: **DSY** · CardiovascularSource: <https://www.510kdatabase.net/k831865/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Jun 10, 1983
Decision date	Oct 19, 1983
Days to decision	131 days
Third-party review	No

APPLICANT

Company	Shiley, Inc.
Location	Mchenry, IL, US
510(k) history	174 submissions · 174 cleared · 1976-1993

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Device record: <https://www.510kdatabase.net/k831865/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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