

**K080621 FASTLOCK, MODEL PC175M01, PC175MCE,
PC005R01**Apr 29, 2008
55 days to decisionK080621 · Product code: **DSA** · Cardiovascular
Source: <https://www.510kdatabase.net/k080621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	Mar 5, 2008
Decision date	Apr 29, 2008
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	European Custom Manufacturing BV
Location	Gemert, NL
Contact	WILLIAM GREENROSE
510(k) history	2 submissions · 2 cleared · 2004-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080621/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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