

**K100518 INSTRUMED VESSEL DILATORS, MODEL
65-7XX,65-9XXX,66-1XXX,65-7048-65-7054**Aug 31, 2010
189 days to decisionK100518 · Product code: **DWP** · Cardiovascular
Source: <https://www.510kdatabase.net/k100518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, Surgical (DWP)
Date received	Feb 23, 2010
Decision date	Aug 31, 2010
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Instrumed International, Inc.
Location	Tuningen, B.W., DE
Contact	MICHAEL MASSONG
510(k) history	7 submissions · 7 cleared · 2004-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100518/> 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 20, 2026