

**K173450 PRESS DUO elite, PRESS DUO elite AG**Feb 7, 2018  
93 days to decisionK173450 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k173450/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Nov 6, 2017
Decision date	Feb 7, 2018
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nemoto Kyorindo Co., Ltd.</b>
Location	Tokyo, JP
Contact	Jim Knipfer
510(k) history	8 submissions · 8 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173450/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026