

**K242212 Disposable Syringe (Kit)**Aug 27, 2024  
29 days to decisionK242212 · Product code: **DXT** · General Hospital  
Source: <https://www.510kdatabase.net/k242212/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jul 29, 2024
Decision date	Aug 27, 2024
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Nemoto Disposable Syringe (Kit)

**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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242212/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026