FDA 510(k) Premarket Notification

K242212 Disposable Syringe (Kit)

CLEARED

Aug 27, 2024
29 days to decision

K242212 · Product code: **DXT** · General Hospital
Source: https://www.510kdatabase.net/k242212/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov