FDA 510(k) Premarket Notification

K183332 “BRAXX” Esophageal Brachytherapy Applicator

CLEARED

Apr 16, 2019
134 days to decision

K183332 · Product code: **JAQ** · Radiology
Source: https://www.510kdatabase.net/k183332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Dec 3, 2018
Decision date	Apr 16, 2019
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Braxx Biotech Co., Ltd.**
Location	Taipei City, TW
Contact	Judy Kao
510(k) history	2 submissions · 2 cleared · 2019-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k183332/ 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 May 26, 2026