

**K243045 “BRAXX” Esophageal Brachytherapy Applicator
(Model: BKMI2001, BKMI2002)**Nov 19, 2024
53 days to decisionK243045 · Product code: **JAQ** · Radiology
Source: <https://www.510kdatabase.net/k243045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Sep 27, 2024
Decision date	Nov 19, 2024
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	ZhengCheng Consulting Limited Company
Contact	Anita Chen

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.netDevice record: <https://www.510kdatabase.net/k243045/>; 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 14, 2026