FDA 510(k) Premarket Notification

K212820 Disposable Semi Automatic Biopsy Instrument

CLEARED

Jul 6, 2022
306 days to decision

K212820 · Product code: **KNW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212820/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 3, 2021
Decision date	Jul 6, 2022
Days to decision	306 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Suzhou Leapmed Healthcare Corporation**
Location	Suzhou, CN
Contact	Yu Zhu
510(k) history	4 submissions · 4 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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