FDA 510(k) Premarket Notification

K220102 MOST-T Autoclave

CLEARED

Oct 12, 2022
273 days to decision

K220102 · Product code: **FLE** · General Hospital
Source: https://www.510kdatabase.net/k220102/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Jan 12, 2022
Decision date	Oct 12, 2022
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Shinva Medical Instrument Co., Ltd.**
Location	Zibo, CN
Contact	Liu Xiaolin
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Osmunda Medical Device Technology, Inc.**
Contact	Olivia Meng

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