

K211890 Promisemed Sharps containerNov 17, 2021
149 days to decisionK211890 · Product code: **MMK** · General Hospital
Source: <https://www.510kdatabase.net/k211890/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Container, Sharps (MMK) |
| Date received | Jun 21, 2021 |
| Decision date | Nov 17, 2021 |
| Days to decision | 149 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Promisemed Hangzhou Meditech Co., Ltd. |
| Location | Hangzhou, CN |
| Contact | Zearou Yang |
| 510(k) history | 34 submissions · 34 cleared · 2017-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|--------------------------------|
| Consulting firm | Vee Care (Asia) Limited |
| Contact | Wei Shan Hsu |

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

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