

K200821 anti-bacterial bandageOct 19, 2020
203 days to decisionK200821 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200821/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Mar 30, 2020 |
| Decision date | Oct 19, 2020 |
| Days to decision | 203 days |
| Third-party review | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Planet (Suzhou) Medical Products Co., Ltd. |
| Location | Suzhou, CN |
| Contact | Frank Zhou |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

REGULATORY CONSULTANT

| | |
|-----------------|--|
| Consulting firm | Linkhope Medical Technology, Inc. |
| Contact | Van Lee |

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/k200821/> 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 June 29, 2026