

K213920 Kangbeier Surgical Mask (Model: KBR-1001)Jan 16, 2022
32 days to decisionK213920 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k213920/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Dec 15, 2021 |
| Decision date | Jan 16, 2022 |
| Days to decision | 32 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Xinxiang Kangbeier Medical Technology Co., Ltd. |
| Location | Changyuan, CN |
| Contact | Shaoju Tian |
| 510(k) history | 2 submissions · 2 cleared · 2022-2023 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Regulatory Technology Services, LLC |
| Contact | Prithul Bom |

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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