

K192671 Hemostatic Xerogel SpongeAug 28, 2020
337 days to decisionK192671 · Product code: **QSY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k192671/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY) |
| Date received | Sep 26, 2019 |
| Decision date | Aug 28, 2020 |
| Days to decision | 337 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Solaplus Biotech Co., Ltd. |
| Location | Wenzhou, CN |
| Contact | Xiangui Shen |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------------|
| Consulting firm | Mid-Link Consulting Co, Ltd. |
| Contact | Diana Hong |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192671/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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