

K221533 Plasma ShieldSep 12, 2022
108 days to decisionK221533 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221533/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | May 27, 2022 |
| Decision date | Sep 12, 2022 |
| Days to decision | 108 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Plasmatica, Ltd. |
| Location | Ra'Anana, IL |
| Contact | Adam Sagiv |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------------------|
| Consulting firm | Mdi Consultants, Inc. |
| Contact | Vaibhav Arvind Rajal |

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/k221533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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