

K933811 MORELLE SOS TREATMENT, MORELLE MAMAPLAST, MORELLE ABDOPLAST

May 12, 1994
281 days to decision

K933811 · Product code: **MDA** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k933811/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Elastomer, Silicone, For Scar Management (MDA) |
| Date received | Aug 4, 1993 |
| Decision date | May 12, 1994 |
| Days to decision | 281 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Pitt Enterprises (Silicone) , Ltd. |
| Location | New Millford, CT, US |
| 510(k) history | 1 submissions · 1 cleared · 1994-1994 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k933811/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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