

K841628 WIREJul 23, 1984
95 days to decisionK841628 · Product code: **HXN** · Orthopedic
Source: <https://www.510kdatabase.net/k841628/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Applier, Cerclage (HXN) |
| Date received | Apr 19, 1984 |
| Decision date | Jul 23, 1984 |
| Days to decision | 95 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Plastafil, Inc. |
| Location | Walker, MI, US |
| 510(k) history | 13 submissions · 13 cleared · 1984-1984 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k841628/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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