

K843544 THE BIBICURE SYS BREAST TONERJan 25, 1985
140 days to decisionK843544 · Product code: **HGY** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k843544/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Breast, Non-powered (HGY) |
| Date received | Sep 7, 1984 |
| Decision date | Jan 25, 1985 |
| Days to decision | 140 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Les Entreprises Bibi, Inc. |
| Location | Montreal H2n1a4, CA |
| Contact | PIA DAMTSIS |
| 510(k) history | 2 submissions · 2 cleared · 1984-1985 |

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