FDA 510(k) Premarket Notification

# K991266 <GENX> EMBRYO TRANSFER CATHETER CC GLIDER

**CLEARED**

Sep 9, 1999
149 days to decision

K991266 · Product code: **MQF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k991266/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Assisted Reproduction (MQF) |
| Date received | Apr 13, 1999 |
| Decision date | Sep 9, 1999 |
| Days to decision | 149 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **<Genx> Intl., Inc.** |
| Location | Madison, CT, US |
| Contact | MICHAEL D CECCHI |
| 510(k) history | 32 submissions · 32 cleared · 1996-2012 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k991266/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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