

K003664 DELFIA NEONATAL IRT KIT, MODEL A005-110Feb 14, 2001
78 days to decisionK003664 · Product code: **CGZ** · Chemistry
Source: <https://www.510kdatabase.net/k003664/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Ion-specific, Chloride (CGZ) |
| Date received | Nov 28, 2000 |
| Decision date | Feb 14, 2001 |
| Days to decision | 78 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Wallac OY |
| Location | Finland, FI |
| Contact | GUNNEL LAAKSONEN |
| 510(k) history | 22 submissions · 21 cleared · 1992-2014 |

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