

**K063086 TRANSFERRIN, SPECICAL CALIBRATOR, SPECITROL AND SPECITROL HIGH CONTROLS**

Aug 8, 2007  
302 days to decision

K063086 · Product code: **DDG** · Immunology  
Source: <https://www.510kdatabase.net/k063086/>

**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Transferrin, Antigen, Antiserum, Control (DDG) |
| Date received         | Oct 10, 2006                                   |
| Decision date         | Aug 8, 2007                                    |
| Days to decision      | 302 days                                       |
| Third-party review    | No   |
| Summary / Statement   | Statement                                      |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Thermo Electron OY</b>             |
| Location       | Vantaa, FI                            |
| Contact        | PAIVI SORMUNEN                        |
| 510(k) history | 9 submissions · 9 cleared · 2006-2007 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k063086/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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