

K173646 FS ErgoDec 19, 2017
22 days to decisionK173646 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k173646/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Extraoral Source, Digital (MUH) |
| Date received | Nov 27, 2017 |
| Decision date | Dec 19, 2017 |
| Days to decision | 22 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Palodex Group OY |
| Location | Tuusula, FI |
| Contact | Anni Lundholm |
| 510(k) history | 10 submissions · 10 cleared · 2012-2024 |

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