

**K984043 QUADRANT TOTAL ETCH**Dec 4, 1998  
21 days to decisionK984043 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k984043/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received         | Nov 13, 1998                       |
| Decision date         | Dec 4, 1998                        |
| Days to decision      | 21 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cavex Holland BV</b>                                 |
| Location       | Rw Haarlem (Holland), NL                                |
| Contact        | BERNARD VAN DUIJN                                       |
| Website        | <a href="https://www.cavex.nl">https://www.cavex.nl</a> |
| 510(k) history | 26 submissions · 26 cleared · 1998-2015                 |

Cavex Holland BV is a dental device manufacturer based in Haarlem, Netherlands. Founded in 1908, the company develops and manufactures impression materials, whitening products, restorative materials, and related dental solutions for professionals and consumers. Cavex has received FDA 510(k) clearances from total submissions, with no denied submissions on record. All cleared devices fall within the dental category. The company's regulatory history spans from 1998 to 2015. Cavex is currently inactive in the FDA 510(k) system, with no new clearances in more than five years; ...

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