

**K162654 mollosil plus**Mar 13, 2017  
171 days to decisionK162654 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k162654/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Resin, Denture, Relining, Repairing, Rebasing (EBI) |
| Date received         | Sep 23, 2016  |
| Decision date         | Mar 13, 2017  |
| Days to decision      | 171 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Detax GmbH &amp; Co. KG</b>        |
| Location       | Amsterdam, NL                         |
| Contact        | Antje Reeps                           |
| 510(k) history | 5 submissions · 5 cleared · 2000-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162654/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 20, 2026