

**K030663 TOKUYAMA SOFRELINER TOUGH**May 29, 2003  
87 days to decisionK030663 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k030663/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Resin, Denture, Relining, Repairing, Rebasing (EBI) |
| Date received         | Mar 3, 2003   |
| Decision date         | May 29, 2003  |
| Days to decision      | 87 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Tokuyama Dental Corporation</b>      |
| Location       | Washington, DC, US                      |
| Contact        | DANIEL J MANELLI                        |
| 510(k) history | 19 submissions · 19 cleared · 2003-2021 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030663/> 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 May 27, 2026