

**K971641 ANTIBACTERIAL GUTTA PERCHA**Jul 21, 1997  
80 days to decisionK971641 · Product code: **EKM** · Dental  
Source: <https://www.510kdatabase.net/k971641/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Gutta-percha (EKM)                 |
| Date received         | May 2, 1997                        |
| Decision date         | Jul 21, 1997                       |
| Days to decision      | 80 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Dr. Howard Martin, P.A.</b>        |
| Location       | Frederick, MD, US                     |
| Contact        | KYLE H SIBINOVIC                      |
| 510(k) history | 3 submissions · 3 cleared · 1997-2006 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971641/> 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 30, 2026