

**K880562 ADDITIONAL CLAIMS TO DENTAL RESTORATIVE
COMP. KIT**Aug 19, 1988
190 days to decisionK880562 · Product code: **DYH** · Dental
Source: <https://www.510kdatabase.net/k880562/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent - SN |
| Submission type | Traditional |
| Device classification | Adhesive, Bracket And Tooth Conditioner, Resin (DYH) |
| Date received | Feb 11, 1988 |
| Decision date | Aug 19, 1988 |
| Days to decision | 190 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Macrochem Corp. |
| Location | Woburn, MA, US |
| Contact | CARLOS M SAMOUR,PHD |
| 510(k) history | 5 submissions · 4 cleared · 1986-1989 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k880562/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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