

K130959 AFTAMED MOUTHWASHApr 4, 2014
364 days to decisionK130959 · Product code: **OLR** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k130959/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oral Wound Dressing (OLR) |
| Date received | Apr 5, 2013 |
| Decision date | Apr 4, 2014 |
| Days to decision | 364 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | AFTAMED GEL; AFTAMED SPRAY; AFTAMED SHIELD; AFTAMED JUNIOR GEL |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bioplax Limited |
| Location | Bellingham, WA, US |
| Contact | PAUL KETTERIDGE |
| 510(k) history | 1 submissions · 1 cleared · 2014-2014 |

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