

**K080424 HYGIA HEALTH SERVICES REPROCESSED LNCS
SENSORS, MODELS HHS-1858, HHS-1862, HHS-1860 AND
HHS-1861**

May 28, 2008
103 days to decision

K080424 · Product code: **NLF** · Anesthesiology
Source: <https://www.510kdatabase.net/k080424/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter, Reprocessed (NLF) |
| Date received | Feb 15, 2008 |
| Decision date | May 28, 2008 |
| Days to decision | 103 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Hygia Health Services, Inc. |
| Location | Birmingham, AL, US |
| Contact | JEROME JAMES |
| 510(k) history | 14 submissions · 14 cleared · 2002-2010 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k080424/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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