

K210969 NulifeNov 3, 2021
217 days to decisionK210969 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k210969/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Surgeon's Gloves (KGO) |
| Date received | Mar 31, 2021 |
| Decision date | Nov 3, 2021 |
| Days to decision | 217 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Mrk Healthcare Pvt, Ltd. |
| Location | Patan, IN |
| Contact | Anil R Dave |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|--|
| Consulting firm | Liberty Management Group , Ltd. |
| Contact | Manoj Zacharias |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210969/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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