

K210051 OTE MPS 045 Multi-purpose Lens Care SolutionMay 26, 2021
138 days to decisionK210051 · Product code: **LPN** · Ophthalmic
Source: <https://www.510kdatabase.net/k210051/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accessories, Soft Lens Products (LPN) |
| Date received | Jan 8, 2021 |
| Decision date | May 26, 2021 |
| Days to decision | 138 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ote North America, LLC |
| Location | Inwood, NY, US |
| Contact | Nathan Rosenberg |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|--|
| Consulting firm | Foresight Regulatory Strategies, Inc. |
| Contact | Ellen M. Beucler |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT03278223****One-month Clinical Evaluation of Oté Sensation Multi-Purpose Solution Care System**

| | |
|-------------------|------------------------------|
| Status | Completed |
| Enrollment | 194 patients (actual) |
| Study sites | 11 sites |
| Condition studied | Myopia; Hyperopia |
| Primary purpose | Other |
| Study type | Interventional |
| Study design | Parallel |
| Masking | Double blind |
| Completion date | Dec 20, 2017 |
| Sponsor | OTE North America (Industry) |

Primary outcome**Comfort**Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03278223