

K210052 Saneso Colonoscope 360-A (Model: with/without Select Band Imaging (SBI) and with/without Dual Band Imaging(DBI)), Saneso Single Camera Colonoscope-A (Model: with/without Select Band Imaging (SBI)), Saneso Gastroscope 360-A (Model: with/without Select Band Imaging (SBI) and with/without Dual Band Imaging(DBI)), Saneso Single Camera Gastroscope-A (Model: with/without Select Band Imaging (SBI))

Apr 1, 2022
448 days to decision

K210052 · Product code: FDF · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k210052/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Colonoscope And Accessories, Flexible/rigid (FDF) |
| Date received | Jan 8, 2021 |
| Decision date | Apr 1, 2022 |
| Days to decision | 448 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Saneso, Inc. |
| Location | Pittsburgh, PA, US |
| Contact | Nitesh Ratnakar |
| 510(k) history | 2 submissions · 2 cleared · 2022-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|---------------------------------------|
| Consulting firm | Elexes Medical Consulting, LLC |
| Contact | Parul Chansoria |

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k210052/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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