DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K182831

Device Name
SabreLine™ Laser Fibers
SabreGuard™ Laser Fibers

Indications for Use *(Describe)*
The SabreLine™ and SabreGuard™ Laser Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm – 2200nm have received regulatory clearance. Coloplast surgical fiber optic laser delivery devices are intended for use with any cleared surgical laser with an SMA 905 connector.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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