510(k) SUMMARY

I. SUBMITTER

510(K) Owner's Name:	Coloplast A/S
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Date Prepared:	October 4, 2018

II. DEVICE

Trade or Proprietary Name:	SabreLine™ and SabreGuard™ Laser Fibers
Common or Usual Name:	Bare Laser Fibers
Classification Name:	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology (21CFR section 878.4810) (Product Code: GEX) Device Class: 2

III. PREDICATE DEVICE

The SabreLine™ and SabreGuard™ Laser Fibers are substantially equivalent in performance, indication, design and materials to the Laser Peripherals, LLC family of Bare Laser Fibers (K170366).

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Coloplast SabreGuard™ and SabreLine™ Laser Fibers are fiber optic laser delivery devices that transmit laser energy to soft and hard tissue in contact and non-contact mode during surgical laser procedures. The devices are 3.0 meters in length and are terminated with a SMA-905 connector on the proximal end.

A laser fiber is made of silica inner core, with a primary and secondary cladding surrounded by a polymeric jacket. The laser fibers are compatible with laser systems operating in wavelengths between 500 nm – 2200 nm. The laser delivery devices are intended for use with any cleared surgical laser with a SMA-905 connector.

Coloplast reference SUNXXX are equipped with a round tip, Coloplast reference SUEXXX are equipped with a radius tip; Coloplast reference SUDXXXX and RUSXXX are equipped with a straight tip.

Single use laser fibers are delivered sterile in a retail box of 3, with an instruction for use in paper version. Reusable laser fibers are delivered sterile in a retail box of 1, with an instruction for use in paper version.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The SabreLine™ and SabreGuard™ Laser Fibers are substantially equivalent in performance, design and materials to the predicate, Laser Peripherals, LLC family of Bare Laser Fibers, cleared under premarket notification number K170366.

The SabreLine™ and SabreGuard™ Laser Fibers are a standard silica core fiber, silica cladding, fluoropolymer coating, and Tefzel buffer. The technological characteristics of the proposed device, which allow use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm – 2200nm have received regulatory clearance, is substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility Testing
Biocompatibility testing was conducted based upon ISO 10993-1 (2009): Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management processand FDA Guidance for Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process - Guidance for Industry and Food and Drug Administration Staff – June 16, 2016. A comprehensive regimen of testing for the SabreLine™ and SabreGuard™ Laser Fibers included:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Material-mediated pyrogenicity

Mechanical Testing
Mechanical testing was completed as follows to verify the product design performance.

- Tip Diameter
- Bend Radius
- Deflected Ureteroscope Bend Navigation Test
- Energy Transfer/Transmission Testing
- Spot Check
- Connector Bond Strength

Sterilization
The SabreLine™ and SabreGuard™ Laser Fibers are sterilized using ethylene oxide in a validated cycle demonstrating a sterility assurance level (SAL) of 10^{-6}.

Packaging and Distribution
The SabreLine™ and SabreGuard™ Laser Fibers were subjected to distribution testing and verification testing to demonstrate that the product and package would be undamaged throughout the product life and maintain the device sterility.
No animal studies or clinical testing were provided to support substantial equivalence between the subject and predicate devices.

VIII. CONCLUSIONS

The SabreLine™ and SabreGuard™ Laser Fibers have been demonstrated to be substantially equivalent to the predicate, Laser Peripherals, LLC family of Bare Laser Fibers based on the non-clinical data provided, similar intended use, materials, design and construction, biocompatibility, and technological characteristics.