DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K192980

Device Name

EOGas 4 Endo-SteriTest

Indications for Use *(Describe)*

The EOGas 4 Endo-SteriTest consists of a self-contained biological indicator inoculated with viable Bacillus atrophaeus bacterial spores that is placed in a dedicated biological indicator receptacle mounted on a gold-colored purge probe in the sterilizer. It monitors the efficacy of the 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.

Critical process parameters for the cycle are summarized in Table 1.

Table 1. Critical parameters for the 6-hour gas exposure in the EOGas 4 Ethylene Oxide Gas Sterilizer

Ethylene Oxide	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
17.6 g ± 5%	50°C ± 3°C	35-90%	6 hours	7 hours

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.

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