

Supplementary information

Advances in vaporized hydrogen peroxide reusable medical device sterilization cycle development: Technology review and patent trends

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Table S1. Summary of the parameters of Flexible cycle of V-PRO® maX 2 sterilizer.

Phase		Initial pressure (Torr)	Final pressure (Torr)	Duration (min)	Comment
Moisture check	Evacuation and moisture verification	-	0.4	-	-
	Conditioning	0.4	< 0.4	-	If moisture available
	Moisture re- verification	-	-	-	If moisture available. Abort if fails.
Sterilize	H ₂ O ₂ injection	0.4	6.3 - 15	-	-
	Hold segment	-	-	2	-
	Air injection	-	500	-	-
	Hold segment	500	500	1	-
	Pressure reduction	500	0.4	-	-
	Re-evacuation and re- sterilization	-	-	-	3 repeats
Aerate	Aeration	1	-	-	-

Table S2. Summary of 510(k) premarket notification clearances of STERRAD 100NX and NX as well as V-Pro Max and S series sterilizers.

Manufacturer	Device name	510(k) number	Decision date	Modification
ASP	Sterrad Nx With Allclear Technology	K220404	05/16/2022	An expansion of existing claims. No cycle modification.
	STERRAD® 100NX Sterilizer with ALLClear Technology	K212174	10/09/2021	An expansion of existing claims. No cycle modification.
	Sterrad NX Sterilizer	K162007	02/16/2017	Vacuum pump and associated mounting components modification. No cycle modification.
	Sterrad® NX Sterilizer With Allclear Technology	K160818	09/27/2016	Addition of Load Conditioning Feature. Do not modify the existing sterilization cycles.
	Sterrad 100NX Sterilizer with Allclear Technology	K160903	09/26/2016	Addition of Load Conditioning Feature. Do not modify the existing sterilization cycles.
	Sterrad NX Sterilizer, Sterrad 100NX Sterilizer	K151725	01/13/2016	Microprocessor module change with no cycle modification.
	Sterrad NX Sterilizer, Sterrad 100NX Sterilizer	K142454	04/03/2015	Software revision and upgraded CPU. No cycle modification.
	Sterrad 100NX Sterilizer Duo Cycle	K111377	09/26/2012	Addition of DUO Cycle.

	Sterrad 100NX Sterilizer	K092622	03/04/2011	Addition of Express Cycle.
	Express Cycle			
Steris	V-Pro Max 2 Low Temperature Sterilization System, V-Pro S2 Low Temperature Sterilization System	K222849	09/30/2022	Same control but using slightly modified boards. No cycle modification.
	V-Pro Max 2 Low Temperature Sterilization System, V-Pro Max Low Temperature Sterilization System	K222093	09/09/2022	Modification of indications for use. No cycle modification.
	V-Pro Max 2 Low Temperature Sterilization System, V-Pro S2 Low Temperature Sterilization System	K222543	08/25/2022	Same control but using refurbished/slightly modified boards. No cycle modification.
	V-Pro S2 Low Temperature Sterilization Systems	K190917	05/09/2019	Modification of indications for use. No cycle modification.
	V-Pro Max 2 Low Temperature Sterilization System, V-Pro Max Low Temperature Sterilization System	K190103	04/05/2019	Modification of indications for use for the Lumen cycle. No cycle modification.

V-Pro Temperature System	S2	Low	K182568	01/03/2019	Modification of indications for use. No cycle modification.
V-Pro Temperature System	Max 2	Low	K172754	02/09/2018	Addition of the Fast Non Lumen Cycle.
V-Pro Temperature System	Max	Low	K172319	01/18/2018	Modifications to labeling. No cycle modification.
V-Pro Temperature System	Max	Low	K162413	03/31/2017	Remove labeling restrictions. No cycle modification.
V-Pro® Temperature	Max	Low	K160433	07/06/2016	Indications differ slightly. No cycle modification.
V-Pro Temperature System	Max	Low	K131120	07/16/2013	Indications of Lumen Cycle updated. No cycle modification.
V-Pro Temperature System	Max	Low	K120632	06/26/2012	Modification of Lumen Cycle claims. No cycle modification.
Amsco V-Pro Temperature System	Max	Low	K112813	12/01/2011	Modification of Lumen Cycle claims. No cycle modification.

Amsco V-Pro Max Low Temperature Sterilization System	K112760	11/22/2011	Modification of Lumen Cycle claims. No cycle modification.
Amsco V-Pro Max Low Temperature Sterilization System	K102330	08/12/2011	Introduction of V-Pro Max by addition of Flexible Cycle.
