

510(k) Number (if known): K960441

Device Name: SteriTec Integraph

Indications For Use:

The Steritec *Integraph* is designed to provide an integrated response to steam sterilization at 132 C for prevacuum sterilizers operating for 3 ½ minutes or longer.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

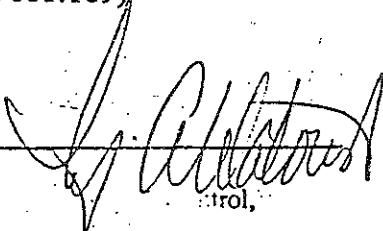
Prescription Use _____
Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter

(Optional Format 1-2-96)

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510(k) K960441

Performance Testing - SteriTec Integrph CI 101

3 Minutes Sterilization Time at:

124°C		128°C			130°C			132°C			134°C		
Pass	Fail	Pass	Fail	Bio	Pass	Fail	Bio	Pass	Fail	Bio	Pass	Fail	Bio
+	-	+	-	+/-	+	-	+/-	+	-	+/-	+	-	+/-
0	275	0	300	1/12	58	250	0/12	308	133	0/12	292	17	0/12
132°C for:													
1 minute		2 minutes			2½ minutes			3 minutes			3½ minutes		
Pass	Fail	Pass	Fail	Bio	Pass	Fail	Bio	Pass	Fail	Bio	Pass	Fail	Bio
+	-	+	-	+/-	+	-	+/-	+	-	+/-	+	-	+/-
0	300	0	292	0/12	50	258	0/12	308	133	0/12	300	0	0/12
4 minutes		Pass	Fail	Bio									
+	-	+	-	+/-									
316	0	0	0	0									

TABLE 1

Notes: Pass=Strip indicates sterilization conditions WERE met.
 Purple ink changes to green on spots 1 and 2.

Fail=Strip indicates sterilization conditions WERE NOT met
 Spots 1 and/or 2 not completely changed to green.

Bio=Biological spore strips. + = Survivors - = No Survivors