

**FDA Approved Autoclaves - May 2020**

510(K) NUMBER	PRODUCT	COMPANY	APPROVAL DATE
K000077	STERIS AMSCO MILLENNIUM STEAM STERILIZER	STERIS Corporation	3/17/2000
K003441	CASTLE MODEL 233HC STEAM STERILIZER	GETINGE/CASTLE INC.	1/2/2001
K003470	EHS SERIES TABLE TOP AUTOCLAVE MODELS 2540 AND 3870	TUTTNAUER CO. LTD.	2/20/2001
K010865	AMSCO CENTURY MEDIUM STERILIZER MODEL CENTURY	STERIS Corporation	5/31/2001
K012573	CASTLE 400HC/500HC SERIES STEAM STERILIZER MODELS 422HC 433HC 522HC AND 533HC	GETINGE/CASTLE INC.	9/5/2001
K014174	HARVEY PV DRY STERILIZER MODEL # ST127325; ST127320; ST127320-33	BARNSTEAD/THERMOLYNE CORP.	2/22/2002
K020590	MODEL 733HC GRAVITY/VACUUM STEAM STERILIZER	GETINGE/CASTLE INC.	3/20/2002
K020747	AMSCO CENTURY MEDIUM STERILIZER 26 X 26	STERIS Corporation	5/17/2002
K021064	QUANTIM 16 AUTOCLAVE	SCICAN	8/8/2002
K021223	BELIMED STEAM STERILIZER MODEL TOP 5000	SAUTER AG	6/26/2002
K021504	TUTTNAUER EHS SERIES TABLE-TOP AUTOCLAVE MODEL 2540	TUTTNAUER USA CO. LTD.	7/25/2002
K022816	W & H LISA STEAM STERILIZER	A-DEC INC.	2/7/2003
K023348	MIDMARK M9 ULTRACLAVE STEAM STERILIZER	MIDMARK CORP.	3/3/2003
K024133	CLS-2000 UNIT	DENTSPLY INTL.	10/1/2003
K030789	AMSCO CENTURY STEAM STERILIZER	STERIS Corporation	3/26/2003
K031259	MODEL 833HC VACUUM/GRAVITY STEAM STERILIZER	GETINGE USA INC	5/12/2003
K032192	PRE-VACUUM AUTOCLAVE WITH STEAM GENERATOR AND VERTICAL SLIDING DOOR MODELS 4472 EP-1V AND 5596 EP-1V	TUTTNAUER USA CO. LTD.	8/12/2004
K033538	BELIMED STEAM STERILIZER TOP 5000 SERIES 4 - 8	SAUTER AG	2/2/2004
K041833	CONSOLIDATED SR AND SSE MC-SERIES STEAM STERILIZER	CONSOLIDATED MACHINE CORP.	12/10/2004
K050263	MILLENNIUM SERIES INCLUDING MILLENNIUM B B+ B2 AND BU	M.O.C.O.M. SRL	11/21/2006
K052532	IMAX 9.5 STERILIZERS	DENTAL X SRL	9/5/2006
K060337	BELIMED STEAM STERILIZER TOP 5000 MODEL 5-5-9	SAUTER AG	3/8/2006
K063681	TECNO-GAZ ANDROMEDA VACUUM CS AUTOCLAVE	MEDILINE ITALIA S.R.L.	6/29/2007
K063711	TUTTNAUER PREVACUUM STEAM HEATED AUTOCLAVE MODELS 6990 SP-1A 66120 SP-1A 69150 SP-2A 69120 L USA SP-2A 69180 SP-2HA	TUTTNAUER CO. LTD.	2/2/2007
K070657	GETINGE 633HC SERIES VACUUM/GRAVITY STEAM STERILIZER	GETINGE SOURCING LLC	4/5/2007
K072087	BELIMED STEAM STERILIZER MODEL TOP 5000 SERIES 24	BELIMED SAUTER AG	10/5/2007
K072466	STATIM 7000 (WITHOUT USB PORT) MODEL 01-702100 STATIM 7000 (WITH USB PORT) MODEL 01-702101	SCICAN LTD.	12/19/2007
K082435	AMSCO EVOLUTION MEDIUM STEAM STERILIZER	STERIS Corporation	12/30/2008
K082817	PRIMUS STEAM STERILIZER MODELS PSS5-G-1 AND PSS5-M	PRIMUS STERILIZER COMPANY LLC.	5/21/2009
K090265	BRAVO AUTOCLAVE MODELS 17 17V AND 21V	SCICAN LTD.	5/15/2009
K090339	BELIMED STEAM STERILIZER TOP 5000 SERIES 8 MODELS: 6-0-12 VS1 AND VS2	BELIMED SAUTER AG	9/23/2009
K090670	MIDMARK M3 ULTRAFast AUTOMATIC STERILIZER	MIDMARK CORP.	7/7/2009

**FDA Approved Autoclaves - May 2020**

510(K) NUMBER	PRODUCT	COMPANY	APPROVAL DATE
K090783	TUTTNAUER ELARA-11 PRE-VACUUM TABLETOP AUTOCLAVE	TUTTNAUER USA CO. LTD.	8/20/2009
K091136	AMSCO EVOLUTION MEDIUM STEAM STERILIZER MODEL HC-900 AND HC-1200	STERIS Corporation	6/29/2009
K091731	AMSCO EVOLUTION MEDIUM STEAM STERILIZER	STERIS Corporation	9/17/2009
K092490	AMSCO EVOLUTION SERIES STEAM STERILIZER MODEL: HC-2000 AND HC-3000	STERIS Corporation	11/4/2009
K093333	PRIMUS STEAM STERILIZER PSS8-AA (16X16X26 MULTI FUNCTIONAL STERILIZER) LAB/LO STERILIZERPRIMUS STEAM STERILIZER PSS8	PRIMUS STERILIZER COMPANY LLC.	4/2/2010
K100622	BELIMED STEAM STERILIZER MODEL MST-V 3-3-6	BELIMED SAUTER AG	8/27/2010
K103504	GETINGE 400HC/500HC SERIES STEAM STERILIZER	GETINGE SOURCING LLC	3/16/2011
K103841	BELIMED STEAM STERILIZER MST-V	SAUTER AG	3/15/2011
K111223	AMSCO CHIMERON SMALL STEAM STERILIZER	STERIS Corporation	9/20/2011
K111736	TUTTNAUER EZ PLUS SERIES ELECTRONIC TABLETOP AUTOCLAVES	TUTTNAUER CO. LTD.	12/8/2011
K112055	AMSCO CHIMERON MEDIUM STEAM STERILIZER	STERIS Corporation	12/16/2011
K112403	AMSCO CHIMERON MEDIUM STEAM STERILIZER	STERIS Corporation	5/8/2012
K112811	SANICLAVE 200	ALTERNATIVE PIONEERING RESEARCH AND DEVELOPMENT	1/11/2012
K112872	STATIM 2000 G4 CASSETTE	SCICAN LTD.	7/10/2012
K120149	SKYRON INTEGRITY 215 STEAM STERILIZER SKYTRON INTEGRITY 215 SG STEAM STERILIZER SAKURA STEAM STERILIZER ASSV-AB09 SAKURA	SAKURA SEIKI CO. LTD.	5/8/2012
K120441	GETINGE 700HC-E SERIES STEAM STERILIZER	GETINGE SOURCING LLC	5/31/2012
K122071	GETINGE 400HC-E / SERIES STEAM STERILIZER	GETINGE SOURCING LLC	3/12/2013
K122625	GETINGE 800HC- SERIES STEAM STERILIZER	GETINGE SOURCING LLC	5/22/2013
K122774	SAKURA STEAM STERILIZER MODEL ASSV-AH06; SAKURA STEAM STERILIZER MODEL ASSV- AH06E; SKYTRON INTEGRITY 175; SKYTRON INTEG	SAKURA SEIKI CO. LTD.	5/9/2013
K122978	SANICLAVE 102 MODEL RS-SC-102	ALTERNATIVE PIONEERING RESEARCH AND DEVELOPMENT	5/23/2013
K130172	BELIMED STEAM STERILIZER MST-V	BELIMED INC.	9/23/2013
K132439	SAKURA STEAM STERILIZER ASSR; -AO12 -AO12W -AO12P-AO12PW / SKYTRON INTEGRITY 270;STEAM STERILIZERVP STEAM STERILIZER	SAKURA SEIKI CO. LTD.	1/6/2014
K140736	STERISAFE HP TABLE-TOP STEAM STERILIZER	MILTON E PEDRAZZI D.D.S. INC.	1/20/2015
K141009	FORT DEFIANCE AUTOMATED STEAM STERILIZER	Fort Defiance Industries Inc.	12/16/2014
K141879	BELIMED STEAM STERILIZER MST-H	SAUTER AG	6/17/2015
K143311	Pre-vacuum Tabletop Autoclave	TUTTNAUER USA CO. LTD.	1/15/2015
K151597	Family of Steam Sterilizers B 28 series	CEFLA S.C.	3/4/2016
K161848	Family of Steam sterilizers B17 B22 Series	CEFLA S.C.	2/23/2017

**FDA Approved Autoclaves - May 2020**

510(K) NUMBER	PRODUCT	COMPANY	APPROVAL DATE
K163337	Midmark and Ritter M9 and M11 UltraClave <sup>®</sup> Automatic Sterilizers and Ritter M9D AutoClave <sup>®</sup> Automatic Sterilizer	Midmark Corporation	8/31/2017
K170228	Belimed Steam Sterilizer MST-H TOP 5000	Belimed AG	5/12/2017
K170304	Astell UMB 220 UMB 230 UMB 240 Autoclaves/sterilizers	Astell Scientific Limited	3/2/2018
K172159	Getinge GSS67N Series Steam Sterilizer	Maquet GmbH	1/30/2018
K172825	MN-111	W&H Sterilization s.r.l.	5/30/2018
K173481	Amsco Evolution Medium Steam Sterilizer	STERIS Corporation	3/9/2018
K173485	Amsco Evolution Medium Steam Sterilizer	STERIS Corporation	2/22/2018
K173490	Amsco Evolution Medium Steam Sterilizer (Models HC-800 and HC-1000)	STERIS Corporation	2/22/2018
K173493	Amsco Evolution Floorloader Steam Sterilizer HC-2000 and HC-3000	STERIS Corporation	2/23/2018
K180272	Saniclave 250	REVOLUTIONARY SCIENCE	7/26/2018
K181456	Tuttnauer Horizontal Models:4472559666906612069120 and 69180 autoclaves	Tuttnauer Ltd.	7/8/2019
K181993	STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R)	Sturdy Industrial Co. Ltd	11/1/2019
K183410	AMSCO 600 Steam Sterilizer	STERIS Corporation	3/27/2019
K190062	STATCLAVE G4 Chamber Autoclave	SciCan Ltd.	7/26/2019
K191896	Belimed Steam Sterilizer MST-H TOP 5000	Belimed AG	10/31/2019
K761032	CRADLING SYSTEM	MEDIN CORP.	1/26/1977
K770372	STERILIZER STEAM CASTLE 3000	CASTLE CO.	4/5/1977
K770536	STEAM STERILIZER 3000	CASTLE CO.	4/29/1977
K770682	STERILIZER SERIES 3000 MODIFICATION TO	CASTLE CO.	5/20/1977
K771229	STERILIZERS 3100 SERIES TRIM LINE	CASTLE CO.	8/2/1977
K781684	STERILIZER EAGLE 2000	AMERICAN STERILIZER CO.	10/24/1978
K792558	CONTAINER SYSTEM	AESCLAP INSTRUMENTS CORP.	12/27/1979
K800080	STERILIZING CASE CAT. NO. 65199	EDWARD WECK INC.	1/28/1980
K801309	RITTER STERILIZER	SYBRON CORP.	6/20/1980
K821591	STEAM STERILIZATION EQUIPMENT	GETINGE INTERNATIONAL INC.	6/22/1982
K823457	NON-PRESSURE AUTOCLAVE FOR STERILIZATION	INTERDENT INC.	2/23/1983
K830931	PORTABLE AUTOCLAVES	ARNOLD & SONS	7/27/1983
K831356	STEAM STERILIZER	ARS ENTERPRISES INC.	7/18/1984
K833837	AMERICAN GOLD SERIES AUTOCLAVE	TUTTNAUER CO. LTD.	1/11/1984
K834152	ETHYLENE OXIDE DETECTOR GLD-1-07	CALNOR OF EL PASEO INC.	3/19/1984
K842631	STERELIS SEALING EQUIPMENT	STERELIS CORP.	7/26/1984
K844649	ELECTRICALLY HEATED STERILIZER STEAM STERILIZER	TAKIZAWA MEDICAL INSTRUMENTS MANUFACTURER	8/5/1985
K850264	TUTTNAUER PRE-VACUUM AUTOCLAVE	TUTTNAUER CO. LTD.	6/4/1985

**FDA Approved Autoclaves - May 2020**

510(K) NUMBER	PRODUCT	COMPANY	APPROVAL DATE
K852113	ARS ENTERPRISES NEW/REMFR'D GP STEAM STERILIZER 81	ARS ENTERPRISES INC.	9/27/1985
K852114	ARS ENTERPRISES PRE-VACUUM STEAM STERILIZER 85000	ARS ENTERPRISES INC.	9/27/1985
K862495	STARCRAFT ELITE AUTOCLAVE	STARCRAFT MEDICAL CORP.	10/22/1986
K870975	MODIFIED CASTLE POWERCLAVE	CASTLE CO.	4/17/1987
K874644	STEAM AUTOCLAVE CONTROL. & DATALOG. BY DATACON	PHARMETICS INC.	1/27/1988
K882465	MODEL 172-P AND 172-N ROTARY SPRAY ARM	BOLING PRECISION COMPONENTS CO.	6/24/1988
K882713	REBUILDING STERILIZERS	MDT CORP. INC.	8/12/1988
K885140	MULTI-PURPOSE CONTROL SYSTEM	COLLIERS STERILIZER SALES & SERVICE CO. INC.	3/29/1989
K890359	RESUBMITTED STC SERIES 8600 AUTOCLAVE	STERILIZER TECHNOLOGIES CORP.	8/7/1989
K893886	MITEK STERILIZATION TRAY	MITEK SURGICAL PRODUCTS INC.	8/21/1989
K895275	MAC LAVE STEAM STERILIZER	MERCHANTS EXPORT DEVELOPMENT CORP.	11/23/1990
K895638	STEAM STERILIZER (AUTOCLAVE) DENTAL	PORTER INSTRUMENT CO. INC.	2/22/1990
K895848	PRESSURE STEAM STERILIZERS	SCIENTIFIC DEVICE LABORATORY INC.	12/11/1989
K900432	MODEL #M8 ELECTRONIC STERILIZER	MIDMARK CORP.	7/27/1990
K901147	JOSLYN STEAM STERILIZER / STEAM MODERNIZATION KIT	JOSLYN VALVE CORP.	11/30/1990
K903096	RACK-IT (R)	VENGO INDUSTRIES INC.	10/1/1990
K903613	HARVARD/LTE BENCHTOP STEAM STERILIZER (AUTOCLAVE)	HARVARD APPARATUS INC.	11/7/1990
K903614	HARVARD/LTE LABORATORY STEAM STERILIZER AUTOCLAVE	HARVARD APPARATUS INC.	12/14/1990
K910241	STATIM CASSETTE AUTOCLAVE	SCICAN	5/3/1991
K910777	MDT/CASTLE MODELS S-8 TABLE TOP STEAM STERILIZER	MDT BIOLOGIC CO.	3/27/1992
K910778	STEAM VACUUM PULSE STERILIZER SYSTEM (SVPSS)	MDT BIOLOGIC CO.	10/28/1991
K910789	KAVOKLAVE STEAM AUTOCLAVE	KAVO AMERICA	8/26/1991
K911206	MAXIMA-10	STIRN INDUSTRIES	11/29/1991
K911322	MODEL #M9 ULTRACLAVE STEAM STERILIZER	MIDMARK CORP.	8/26/1991
K912471	EAGLE 3000 SDS	AMSCO CO.	6/26/1992
K915054	STATIM CASSETT AUTOCLAVE MODIFICATION	SCICAN	8/4/1992
K920293	DAVIS AND GECK HANDHELD INST. STERILIZATION TRAY	DAVIS & GECK INC.	4/21/1992
K920478	TUTTNAUER LSI (AUTOMATIC)	TUTTNAUER CO. LTD.	7/8/1993
K921613	STERILIZER SURG INSTR/DRESSING #6530-01-306-9510	DEPT. OF THE ARMY	1/29/1993
K924596	SES-2012 AUTOMATIC STEAM STERILIZER	PORTER INSTRUMENT CO. INC.	4/15/1994
K924955	MDT/HARVEY MC-8 AND MC-10	MDT CORP. INC.	10/15/1993

**FDA Approved Autoclaves - May 2020**

510(K) NUMBER	PRODUCT	COMPANY	APPROVAL DATE
K926185	PRIMUS PSS SERIES STERILIZERS	PRIMUS STERILIZER CO. INC.	5/9/1994
K936181	MIDMARK M-11 ULTRACLAVE STEAM STERILIZER	MIDMARK CORP.	11/30/1994
K942989	OCR II & OCM II	CHAMBERMAID PRODUCTS CO.	7/7/1995
K944036	STERIMASTER AUTOCLAVE	SCICAN	10/2/1996
K945117	DELTA	PELTON & CRANE CO.	2/28/1997
K950341	BARNARD & ASSOCIATES REMANUFACTURED GENERAL PURPOSE VACUUM OR LABORATORY STERILIZER	BARNARD AND ASSOC.	4/19/1995
K951273	BUXTON BUILT STERILIZER BUXTON BUILT RECONDITIONED STERILIZER	BUXTON MEDICAL SERVIC CORP.	8/8/1995
K951557	EASTERCLAVE	EASTER SERVICES INC.	9/29/1995
K953938	STERILEMAX	BARNSTEAD/THERMOLYNE CORP.	1/30/1997
K954142	STERRADD STERILIZATION SYSTEM	ADVANCED STERILIZATION PRODUCTS	6/6/1997
K954736	ACCESS (POWERCLAVE)	MDT BIOLOGIC CO.	8/15/1996
K961230	EASTERCLAVE	EASTER SERVICES INC.	6/27/1996
K962179	STAT IM 5000 CASSETTE AUTOCLAVE	SCICAN	1/13/1997
K962282	TUTTNAUER PREVACUUM TABLE AUTOCLAVE	TUTTNAUER USA CO. LTD.	11/12/1997
K962755	STRYKER ENCORE STERILIZER	STRYKER CORP.	3/4/1997
K962903	PRESTIGE MEDICAL SERIES 2100 CLINICAL AUTOCLAVE	PRESTIGE MEDICAL CORP.	3/3/1998
K964332	EAGLE CENTURY STEAM STERILIZER	AMSCO INTL. INC.	6/1/1998
K970907	CASTLE SERIES 100 STEAM STERILIZERS (STRAIGHTLINE)	GETINGE/CASTLE INC.	11/12/1997
K973225	CASTLE SERIES 200 STEAM STERILIZER (POWERCLAVE)	GETINGE/CASTLE INC.	2/10/1998
K973550	TUTTNAUER TABLE-TOP AUTOCLAVE	TUTTNAUER USA CO. LTD.	10/29/1997
K980014	THE SYSTEM 2S STEAM STERILIZER	STERIS Corporation	5/15/1998
K982332	STERIS TEN SIXTEEN STEAM STERILIZER	STERIS Corporation	1/20/1999
K983679	STATIM 5000 CASSETTE AUTOCLAVE	SCICAN	1/4/1999
K990189	MODIFICATION OF: MIDMARK M-11 ULTRACLAVE STEAM STERILIZER	MIDMARK CORP.	4/19/1999
K991575	PRIMUS STEAM STERILIZERS	PRIMUS STERILIZER CO. INC.	12/3/1999
K992744	MIDMARK M4*9 EASYCLAVE STEAM STERILIZER	MIDMARK CORP.	1/10/2000
K993856	TUTTNAUER ELECTRONIC AUTOCLAVE MODELS E EA EK EKA EP	TUTTNAUER USA CO. LTD.	2/9/2001
K994314	CASTLE SERIES 100HC STEAM STERILIZERS	GETINGE/CASTLE INC.	2/16/2000