

510(K) NUMBER	PRODUCT	COMPANY	APPROVAL DATE
K260254	Enbio PRO	Enbio Group AG	2/26/2026
K252307	Getinge GSS67N Series Steam Sterilizer	Maquet GmbH (A Getinge Group Company)	1/22/2026
K250168	Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer	Lucas Lifecare	12/30/2025
K250164	Cassette Autoclave (ACA5)	Guangzhou Ajax Medical Equipment Co. Ltd.	8/14/2025
K243994	Steam Sterilizer (2545D)	Ningbo Ican Machines Co. Ltd.	6/6/2025
K243801	FRONT-LINE Field Sterilizer (FL135)	Fort Defiance Industries LLC	3/7/2025
K233026	Midmark Smart M9Â® Sterilizer Midmark Smart M11Â® Sterilizer	Midmark Corporation	4/4/2024
K233504	Lexa MINI (RIS-303 RIS-305)	W&H Sterilization S.R.L.	2/8/2024
K233132	PRIMUS Healthcare Sterilizer (Model PSS11-HA & PSS11-HB)	Primus Sterilizer Company LLC	12/19/2023
K232658	T-Top 10 & T-Top T-Top 11	Tuttnauer U.S.A Co Ltd.	11/27/2023
K232485	AMSCO 600 Steam Sterilizer	Steris	9/13/2023
K231489	Sturdy Autoclave Super Microm	Sturdy Industrial Co. Ltd.	6/21/2023
K223858	Lexa MINI (RIS-303 RIS-305)	W&H Sterilization S.R.L.	5/5/2023
K221474	PRIMUS Healthcare Sterilizer (Model PSS11-HC)	Primus Sterilizer Company LLC	2/10/2023
K213545	Steelco VS Series Steam Sterilizers models 262839 262851 262869	Steelco S.P.A.	2/2/2023
K222608	Tuttnauer Pre-vacuum Steam Sterilizer models 3870HSG and 3870HSG-WS	Tuttnauer Ltd.	12/16/2022
K220102	MOST-T Autoclave	Shinva Medical Instrument Co. Ltd.	10/12/2022
	AMSCO 600 Steam Sterilizer V-PRO maX 2 Low Temperature Sterilization System V-PRO s2 Low Temperature Sterilization System V-PRO 60 Low Temperature Sterilization System RAS 12 Rack RAS 12 Long Rack RAS Cycle of		
K222849	the AMSCO 7052HP and 7053HP Single Chamber Washer Disinfector	Steris	9/30/2022
K221227	Tuttnauer Horizontal autoclave series model: 4472 5596 6690 66120	Tuttnauer Ltd.	9/20/2022
	AMSCO 600 Steam Sterilizer V-PRO maX 2 Low Temperature Sterilization System V-PRO s2 Low Temperature Sterilization System RAS 12 Rack RAS 12 Long Rack RAS Cycle of the AMSCO 7052HP and 7053HP Single Chamber		
K222543	Washer Disinfector	Steris	8/25/2022
K213758	Lexa PLUS RIS-311	W&H Sterilization S.R.L.	8/19/2022
K220736	Consolidated HC Steam Sterilizer	Consolidated Machine Corp.	8/1/2022
K214120	GSS610N21 Series Steam Sterilizer	Maquet GmbH	5/18/2022
K214057	STATIM 6000B Vacuum Autoclave	Scican Ltd.	3/31/2022
	Fort Defiance Industries FRONT-LINE Field Sterilizer FL120 Fort Defiance		
K213457	Industries FRONT-LINE Field Sterilizer FL135	Fort Defiance Industries LLC	3/2/2022
K213991	Enbio S	Enbio Group AG	2/22/2022
K213080	T-Edge 10 T-Edge 11	Tuttnauer Ltd.	1/4/2022
K210279	Enbio S	Enbio Group AG	10/29/2021
K212424	AMSCO 400 Small Steam Sterilizers AMSCO 400 Medium Steam Sterilizers	STERIS Corporation	10/28/2021
K211500	AMSCO 600 Medium Steam Sterilizer	STERIS Corporation	8/25/2021
K210326	Bravo G4 Chamber Autoclave	Scican Ltd.	7/1/2021

K201927	Getinge GSS610N Series Steam Sterilizer Amsco Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200)Evolution Automated Loading and Unloading System (ALUS); Amsco EvolutionMedium Steam Sterilizer (Models HC-600 and HC-1500)Evolution Automated Loading and Unloading System (ALUS); Amsco EvolutionMedium Steam Sterilizer (Models HC-800 and HC-1000)Evolution Automated Loading and Unloading System (ALUS)	Maquet GmbH	3/1/2021
K203061	STATClave G4 Chamber Autoclave	STERIS Corporation	11/6/2020
K192910	STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R)	Scican Ltd.	6/19/2020
K181993	Belimed Steam Sterilizer MST-H TOP 5000	Sturdy Industrial Co. Ltd.	11/1/2019
K191896	STATCLAVE G4 Chamber Autoclave	Belimed AG	10/31/2019
K190062	Tuttnauer Horizontal Models:4472559666906612069120 and 69180	Scican Ltd.	7/26/2019
K181456	AMSCO 600 Steam Sterilizer	Tuttnauer Ltd.	7/8/2019
K183410	Saniclave 250	STERIS Corporation	3/27/2019
K180272	MN-111	Revolutionary Science	7/26/2018
K172825	Amsco Evolution Medium Steam Sterilizer	W&H Sterilization S.R.L.	5/30/2018
K173481	Astell UMB 220 UMB 230 UMB 240 Autoclaves/sterilizers	STERIS Corporation	3/9/2018
K170304	Amsco Evolution Floorloader Steam Sterilizer HC-2000 and HC-3000	Astell Scientific Limited	3/2/2018
K173493	Amsco Evolution Medium Steam Sterilizer	STERIS Corporation	2/23/2018
K173485	Amsco Evolution Medium Steam Sterilizer (Models HC-800 and HC-1000)	STERIS Corporation	2/22/2018
K173490	Getinge GSS67N Series Steam Sterilizer	STERIS Corporation	2/22/2018
K172159	Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers and Ritter	Maquet GmbH	1/30/2018
K163337	M9D AutoClave® Automatic Sterilizer	Midmark Corporation	8/31/2017
K170228	Belimed Steam Sterilizer MST-H TOP 5000	Belimed AG	5/12/2017
K161848	Family of Steam sterilizers B17 B22 Series	Cefla S.C.	2/23/2017
K151597	Family of Steam Sterilizers B 28 series	Cefla S.C.	3/4/2016
K141879	BELIMED STEAM STERILIZER MST-H	Sauter AG	6/17/2015
K140736	STERISAFE HP TABLE-TOP STEAM STERILIZER	Milton E Pedrazzi D.D.S. Inc.	1/20/2015
K143311	Pre-vacuum Tabletop Autoclave	Tuttnauer U.S.A Co Ltd.	1/15/2015
K141009	FORT DEFIANCE AUTOMATED STEAM STERILIZER SAKURA STEAM STERILIZER ASSR; -AO12 -AO12W -AO12P-AO12PW / SKYTRON	Fort Defiance Industries Inc.	12/16/2014
K132439	INTEGRITY 270;STEAM STERILIZERVP STEAM STERILIZER	Sakura Seiki Co. Ltd.	1/6/2014
K130172	BELIMED STEAM STERILIZER MST-V	Belimed Inc.	9/23/2013
K122978	SANICLAVE 102 MODEL RS-SC-102	Alternative Pioneering Research and Development	5/23/2013
K122625	GETINGE 800HC- SERIES STEAM STERILIZER SAKURA STEAM STERILIZAER MODEL ASSV-AH06; SAKURA STEAM STERILIZER	Getinge Sourcing LLC	5/22/2013
K122774	MODEL ASSV-AH06E; SKYTRON INTEGRITY 175; SKYTRON INTEG	Sakura Seiki Co. Ltd.	5/9/2013
K122071	GETINGE 400HC-E / SERIES STEAM STERILIZER	Getinge Sourcing LLC	3/12/2013
K112872	STATIM 2000 G4 CASSETTE	Scican Ltd.	7/10/2012
K120441	GETINGE 700HC-E SERIES STEAM STERILIZER	Getinge Sourcing LLC	5/31/2012

K112403	AMSCO CHIMERON MEDIUM STEAM STERILIZER SKYRON INTEGRITY 215 STEAM STERILIZER SKYTRON INTEGRITY 215 SG	STERIS Corporation	5/8/2012
K120149	STEAM STERILIZER SAKURA STEAM STERILIZER ASSV-AB09 SAKURA	Sakura Seiki Co. Ltd.	5/8/2012
K112811	SANICLAVE 200	Alternative Pioneering Research and Development	1/11/2012
K112055	AMSCO CHIMERON MEDIUM STEAM STERILIZER	STERIS Corporation	12/16/2011
K111736	TUTTNAUER EZ PLUS SERIES ELECTRONIC TABLETOP AUTOCLAVES	Tuttnauer Co. Ltd.	12/8/2011
K111223	AMSCO CHIMERON SMALL STEAM STERILIZER	STERIS Corporation	9/20/2011
K103504	GETINGE 400HC/500HC SERIES STEAM STERILIZER	Getinge Sourcing LLC	3/16/2011
K103841	BELIMED STEAM STERILIZER MST-V	Sauter AG	3/15/2011
K100622	BELIMED STEAM STERILIZER MODEL MST-V 3-3-6 PRIMUS STEAM STERILIZER PSS8-AA (16X16X26 MULTI FUNCTIONAL STERILIZER) LAB/LO STERILIZERPRIMUS STEAM STERILIZER PSS8	Belimed Sauter AG	8/27/2010
K093333		Primus Sterilizer Company LLC	4/2/2010
K092490	AMSCO EVOLUTION SERIES STEAM STERILIZER MODEL: HC-2000 AND HC-	STERIS Corporation	11/4/2009
K090339	BELIMED STEAM STERILIZER TOP 5000 SERIES 8 MODELS: 6-0-12 VS1 AND	Belimed Sauter AG	9/23/2009
K091731	AMSCO EVOLUTION MEDIUM STEAM STERILIZER	STERIS Corporation	9/17/2009
K090783	TUTTNAUER ELARA-11 PRE-VACUUM TABLETOP AUTOCLAVE	Tuttnauer U.S.A Co Ltd.	8/20/2009
K090670	MIDMARK M3 ULTRAFast AUTOMATIC STERILIZER	Midmark Corp.	7/7/2009
K091136	AMSCO EVOLUTION MEDIUM STEAM STERILIZER MODEL HC-900 AND HC-	STERIS Corporation	6/29/2009
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
K082435	AMSCO EVOLUTION MEDIUM STEAM STERILIZER STATIM 7000 (WITHOUT USB PORT) MODEL 01-702100 STATIM 7000 (WITH USB PORT) MODEL 01-702101	STERIS Corporation	12/30/2008
K072466		Scican Ltd.	12/19/2007
K072087	BELIMED STEAM STERILIZER MODEL TOP 5000 SERIES 24	Belimed Sauter AG	10/5/2007
K063681	TECNO-GAZ ANDROMEDA VACUUM CS AUTOCLAVE	Mediline Italia S.R.L.	6/29/2007
K070657	GETINGE 633HC SERIES VACUUM/GRAVITY STEAM STERILIZER TUTTNAUER PREVACUUM STEAM HEATED AUTOCLAVE MODELS 6990 SP-1A 66120 SP-1A 69150 SP-2A 69120 L USA SP-2A 69180 SP-2HA	Getinge Sourcing LLC	4/5/2007
K063711		Tuttnauer Co. Ltd.	2/2/2007
K050263	MILLENNIUM SERIES INCLUDING MILLENNIUM B B+ B2 AND BU	M.O. Com S.R.L.	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
K041833	CONSOLIDATED SR AND SSE MC-SERIES STEAM STERILIZER PRE-VACUUM AUTOCLAVE WITH STEAM GENERATOR AND VERTICAL SLIDING DOOR MODELS 4472 EP-1V AND 5596 EP-1V	Consolidated Machine Corp.	12/10/2004
K032192		Tuttnauer U.S.A Co Ltd.	8/12/2004
K033538	BELIMED STEAM STERILIZER TOP 5000 SERIES 4 - 8	Sauter AG	2/2/2004
K024133	CLS-2000 UNIT	Dentsply Intl.	10/1/2003
K031259	MODEL 833HC VACUUM/GRAVITY STEAM STERILIZER	Getinge USA Inc.	5/12/2003
K030789	AMSCO CENTURY STEAM STERILIZER	STERIS Corporation	3/26/2003
K023348	MIDMARK M9 ULTRACLAVE STEAM STERILIZER	Midmark Corp.	3/3/2003
K022816	W & H LISA STEAM STERILIZER	A-Dec Inc.	2/7/2003

K021064	QUANTIM 16 AUTOCLAVE	Scican	8/8/2002
K021504	TUTTNAUER EHS SERIES TABLE-TOP AUTOCLAVE MODEL 2540	Tuttnauer U.S.A Co Ltd.	7/25/2002
K021223	BELIMED STEAM STERILIZER MODEL TOP 5000	Sauter AG	6/26/2002
K020747	AMSCO CENTURY MEDIUM STERILIZER 26 X 26	STERIS Corporation	5/17/2002
K020590	MODEL 733HC GRAVITY/VACUUM STEAM STERILIZER	Getinge/Castle Inc.	3/20/2002
K014174	HARVEY PV DRY STERILIZER MODEL # ST127325; ST127320; ST127320-33 CASTLE 400HC/500HC SERIES STEAM STERILIZER MODELS 422HC 433HC	Barnstead/Thermolyne Corp.	2/22/2002
K012573	522HC AND 533HC	Getinge/Castle Inc.	9/5/2001
K010865	AMSCO CENTURY MEDIUM STERILIZER MODEL CENTURY	STERIS Corporation	5/31/2001
K003470	EHS SERIES TABLE TOP AUTOCLAVE MODELS 2540 AND 3870	Tuttnauer Co. Ltd.	2/20/2001
K993856	TUTTNAUER ELECTRONIC AUTOCLAVE MODELS E EA EK EKA EP	Tuttnauer U.S.A Co Ltd.	2/9/2001
K003441	CASTLE MODEL 233HC STEAM STERILIZER	Getinge/Castle Inc.	1/2/2001
K000077	STERIS AMSCO MILLENNIUM STEAM STERILIZER	STERIS Corporation	3/17/2000
K994314	CASTLE SERIES 100HC STEAM STERILIZERS	Getinge/Castle Inc.	2/16/2000
K992744	MIDMARK M4*9 EASYCLAVE STEAM STERILIZER	Midmark Corp.	1/10/2000
K991575	PRIMUS STEAM STERILIZERS	Primus Sterilizer Co. Inc.	12/3/1999
K990189	MODIFICATION OF: MIDMARK M-11 ULTRACLAVE STEAM STERILIZER	Midmark Corp.	4/19/1999
K982332	STERIS TEN SIXTEEN STEAM STERILIZER	STERIS Corporation	1/20/1999
K983679	STATIM 5000 CASSETTE AUTOCLAVE	Scican	1/4/1999
K964332	EAGLE CENTURY STEAM STERILIZER	Amsco Intl. Inc.	6/1/1998
K980014	THE SYSTEM 2S STEAM STERILIZER	STERIS Corporation	5/15/1998
K962903	PRESTIGE MEDICAL SERIES 2100 CLINICAL AUTOCLAVE	Prestige Medical Corp.	3/3/1998
K973225	CASTLE SERIES 200 STEAM STERILIZER (POWERCLAVE)	Getinge/Castle Inc.	2/10/1998
K962282	TUTTNAUER PREVACUUM TABLE AUTOCLAVE	Tuttnauer U.S.A Co Ltd.	11/12/1997
K970907	CASTLE SERIES 100 STEAM STERILIZERS (STRAIGHTLINE)	Getinge/Castle Inc.	11/12/1997
K973550	TUTTNAUER TABLE-TOP AUTOCLAVE	Tuttnauer U.S.A Co Ltd.	10/29/1997
K954142	STERRADD STERILIZATION SYSTEM	Advanced Sterilization Products	6/6/1997
K962755	STRYKER ENCORE STERILIZER	Stryker Corp.	3/4/1997
K945117	DELTA	Pelton & Crane Co.	2/28/1997
K953938	STERILEMAX	Barnstead/Thermolyne Corp.	1/30/1997
K962179	STAT IM 5000 CASSETTE AUTOCLAVE	Scican	1/13/1997
K944036	STERIMASTER AUTOCLAVE	Scican	10/2/1996
K954736	ACCESS (POWERCLAVE)	Mdt Biologic Co.	8/15/1996
K961230	EASTERCLAVE	Easter Services Inc.	6/27/1996
K951557	EASTERCLAVE	Easter Services Inc.	9/29/1995
K951273	BUXTON BUILT STERILIZER BUXTON BUILT RECONDITIONED STERILIZER	Buxton Medical Servic Corp.	8/8/1995
K942989	OCR II & OCM II BARNARD & ASSOCIATES REMANUFACTURED GENERAL PURPOSE VACUUM OR LABORATORY STERILIZER	Chambermaid Products Co.	7/7/1995
K950341		Barnard and Assoc.	4/19/1995
K936181	MIDMARK M-11 ULTRACLAVE STEAM STERILIZER	Midmark Corp.	11/30/1994

K926185	PRIMUS PSS SERIES STERILIZERS	Primus Sterilizer Co. Inc.	5/9/1994
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
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
K915054	STATIM CASSETT AUTOCLAVE MODIFICATION	Scican	8/4/1992
K912471	EAGLE 3000 SDS	Amsco Co.	6/26/1992
K920293	DAVIS AND GECK HANDHELD INST. STERILIZATION TRAY	Davis & Geck Inc.	4/21/1992
K910777	MDT/CASTLE MODELS S-8 TABLE TOP STEAM STERILIZER	Mdt Biologic Co.	3/27/1992
K911206	MAXIMA-10	Stirn Industries	11/29/1991
K910778	STEAM VACUUM PULSE STERILIZER SYSTEM (SVPSS)	Mdt Biologic Co.	10/28/1991
K910789	KAVOKLAVE STEAM AUTOCLAVE	Kavo America	8/26/1991
K911322	MODEL #M9 ULTRACLAVE STEAM STERILIZER	Midmark Corp.	8/26/1991
K910241	STATIM CASSETTE AUTOCLAVE	Scican	5/3/1991
K903614	HARVARD/LTE LABORATORY STEAM STERILIZER AUTOCLAVE	Harvard Apparatus Inc.	12/14/1990
K901147	JOSLYN STEAM STERILIZER / STEAM MODERNIZATION KIT	Joslyn Valve Corp.	11/30/1990
K895275	MAC LAVE STEAM STERILIZER	Merchants Export Development Corp.	11/23/1990
K903613	HARVARD/LTE BENCHTOP STEAM STERILIZER (AUTOCLAVE)	Harvard Apparatus Inc.	11/7/1990
K903096	RACK-IT (R)	Vengo Industries Inc.	10/1/1990
K900432	MODEL #M8 ELECTRONIC STERILIZER	Midmark Corp.	7/27/1990
K895638	STEAM STERILIZER (AUTOCLAVE) DENTAL	Porter Instrument Co. Inc.	2/22/1990
K895848	PRESSURE STEAM STERILIZERS	Scientific Device Laboratory Inc.	12/11/1989
K893886	MITEK STERILIZATION TRAY	Mitek Surgical Products Inc.	8/21/1989
K890359	RESUBMITTED STC SERIES 8600 AUTOCLAVE	Sterilizer Technologies Corp.	8/7/1989
K885140	MULTI-PURPOSE CONTROL SYSTEM	Colliers Sterilizer Sales & Service Co. Inc.	3/29/1989
K882713	REBUILDING STERILIZERS	Mdt Corp. Inc.	8/12/1988
K882465	MODEL 172-P AND 172-N ROTARY SPRAY ARM	Boling Precision Components Co.	6/24/1988
K874644	STEAM AUTOCLAVE CONTROL. & DATALOG. BY DATACON	Pharmetics Inc.	1/27/1988
K870975	MODIFIED CASTLE POWERCLAVE	Castle Co.	4/17/1987
K862495	STARCRAFT ELITE AUTOCLAVE	Starcraft Medical Corp.	10/22/1986
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
K844649	ELECTRICALLY HEATED STERILIZER STEAM STERILIZER	Takizawa Medical Instruments Manufacturer	8/5/1985
K850264	TUTTNAUER PRE-VACUUM AUTOCLAVE	Tuttnauer Co. Ltd.	6/4/1985
K842631	STERELIS SEALING EQUIPMENT	Sterelis Corp.	7/26/1984
K831356	STEAM STERILIZER	Ars Enterprises Inc.	7/18/1984
K834152	ETHYLENE OXIDE DETECTOR GLD-1-07	Calnor of EL Paseo Inc.	3/19/1984
K833837	AMERICAN GOLD SERIES AUTOCLAVE	Tuttnauer Co. Ltd.	1/11/1984
K830931	PORTABLE AUTOCLAVES	Arnold & Sons	7/27/1983
K823457	NON-PRESSURE AUTOCLAVE FOR STERILIZATION	Interdent Inc.	2/23/1983

K821591	STEAM STERILIZATION EQUIPMENT	Getinge International Inc.	6/22/1982
K801309	RITTER STERILIZER	Sybron Corp.	6/20/1980
K800080	STERILIZING CASE CAT. NO. 65199	Edward Weck Inc.	1/28/1980
K792558	CONTAINER SYSTEM	Aesculap Instruments Corp.	12/27/1979
K781684	STERILIZER EAGLE 2000	American Sterilizer Co.	10/24/1978
K771229	STERILIZERS 3100 SERIES TRIM LINE	Castle Co.	8/2/1977
K770682	STERILIZER SERIES 3000 MODIFICATION TO	Castle Co.	5/20/1977
K770536	STEAM STERILIZER 3000	Castle Co.	4/29/1977
K770372	STERILIZER STEAM CASTLE 3000	Castle Co.	4/5/1977
K761032	CRADLING SYSTEM	Medin Corp.	1/26/1977