CROSSTEX™
A CANTEL MEDICAL COMPANY

General and Quality System Information Guide – Industrial Division

Crosstex | Industrial is a division of Crosstex International, a Cantel Medical Company (NYSE: CMN). SPSmedical, based in Rush, NY, and founded in 1987, dedicated its core business to the healthcare industry. In 2012, SPSmedical became a wholly-owned subsidiary of Crosstex International, and part of the Cantel Medical family of infection control-based companies.

We are a leading global manufacturer of infection control and sterilization assurance products. We create high quality, innovative products, the majority of which are manufactured in the United States. Our broad range of products include the following key product lines: Biological Indicators, Chemical Indicators, Quality Control Test Suspensions, Sterilization Pouches and Tubes, Custom Indicator Labels, Face Masks and High-Level Disinfectants.

Our global market segments include medical device, pharmaceutical, contract sterilizer, laboratory, food and beverage and biotechnology companies which we serve through a worldwide distribution network.

Crosstex's infection control and sterilization assurance products are manufactured in FDA regulated facilities. In June 2016, our facility in Rush, New York, was awarded a Quality Management System certification to EN ISO 13485:2012 by the National Standards Authority of Ireland. In March 2017, our facility in Cuba, New York, was added to that certification. This certification was granted based in part on our strong management and production principles, including a clear customer-first philosophy and a commitment to continual improvement and internal review.

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Crosstex International, Inc. | Industrial Markets
6789 W. Henrietta Road, Rush, NY 14543 | T 800.860.1888 | F 419.666.1715 | E productorders@crosstex.com | www.crosstex.com

Part 1 / Supplier and Contact Information		
Company Name:	Crosstex International, Inc.	
Corporate Headquarters Address:	Crosstex International, Inc., 10 Ranick Road, Hauppauge, NY 11788 USA	
Industrial Markets Division:	Customer Service, Sales, Marketing, R&D, Technical Support:	Crosstex Industrial Division 959 Illinois Avenue, Suite B, Maumee, OH 43537 USA
Manufacturing Locations:	Manufacture and shipping of pouches and masks:	Crosstex International, Inc. 10 Ranick Road Hauppauge, NY 11788 USA
	Manufacture and primary packaging of most biological indicators:	SPSmedical Supply Corp., a wholly owned subsidiary of Crosstex 31 Water Street Cuba, NY 14727 USA
	Manufacture of some chemical indicators and hand-inoculated biological indicators; final packaging, inspection, storage and shipping for most product lines:	SPSmedical Supply Corp., a wholly owned subsidiary of Crosstex 6789 W. Henrietta Road Rush, NY 14543 USA
Website:	www.crosstex.com	
New Order Placement & Customer Service email:	productorders@crosstex.com	
Telephone:	800-860-1888 or 567-803-1220	
Fax:	419-666-1715	

Part 2 / General Information	
Company Founding Year:	1953
Parent Company:	Cantel Medical Corporation, a publicly-held company (NYSE: CMN)
Parent Company Address:	150 Clove Road - 9th Floor, Little Falls, New Jersey 07424 USA
Business Type:	Corporation
Industry:	Healthcare
Primary markets served:	Industrial, Primary Care, Acute Care, Ambulatory, Veterinarian, Tattoo, Pharma, and Validation Labs
USA classification of products:	Biological and Chemical Indicators are considered Class II medical devices by the US FDA
Core technologies / expertise:	Propagation of source crops; manufacture of various biological indicator configurations; development of environmentally friendly, water-based inks
No. of employees:	~200
No. of QA/QC employees:	7
No. of manufacturing employees:	85
No. administrative employees:	40
No. of engineering employees:	2
No. of R&D employees:	3
Ratio of supervisors to production employees:	~1:10
Facility size:	50,000 sq. ft. manufacturing space; 12,000 sq. ft. office space

Part 2 / General Information	
Warehouse size:	38,000 sq. ft.
% capacity utilized:	~30%
No. of shifts:	2
No. of buildings:	1 at each site
Open to hosting an on-site audit:	Yes, on-site audits are welcomed under certain circumstances. For more details, please contact either of the following: • Jennifer Griffin, Sr. QSC Specialist, jgriffin@cantelmedical.com • David Adams, Quality Manager, dadams@spsmedical.com

Part 3 / Financial Information			
Dunn & Bradstreet Number:	057728685 (headquarters)		
Tax Identification Number:	11-3048770		
Primary NAICS code:	339113		
Delivery Terms:	FOB Shipping Point / EX Works		
Standard Payment Terms:	Net 30 Days, make checks payable to Crosstex		
Bank name:	Bank of America		
Bank Address / Routing Number:	ACH/EFT	70 Batterson Park Rd, Farmington, CT06032	031202084
	Domestic	100 West 33rd St., New York City, NY 10001	026009593
Bank account number:	383011376893		
Swift code number:	BOFAUS3N		
Standard lead-time	1-2 weeks for standard product		
Typical products cost breakdowns:	Material: 55%	Labor: 35%	Overhead: 10%

Part 4 / Company Contacts			
Names and titles of top management:	Reference *CSOP 024-2_Crosstex-SPSmedical_ Organization Chart,* available upon request, for more information regarding our company structure than given below.		
Name:	*Title:*	*Email:*	*Phone:*
Gary Steinberg	President, CEO	garys@crosstex.com	-
John Hughes	VP and General Manager	jhughes@spsmedical.com	585-359-0130
Dave Adams	Quality Assurance Manager	dadams@spsmedical.com	585-359-0130
Pablo Martinez	Sr. Manager, Regulatory Affairs	pablom@spsmedical.com	585-359-0130

Part 5 / Certifications and Regulatory Information		
21 CFR 820 (GMP):	Registered with the FDA as a medical device establishment, registration numbers 1319130 (Rush, NY) and 1317154 (Cuba, NY)	
Most recent FDA inspection:	July 12-17, 2017	All findings have been addressed and action items implemented. The associated CAPA have all been closed.
ISO 13485 Certificate Number:	MD19.4985	
Regulatory body:	NSAI, National Standards Authority of Ireland	
Certification Granted:	June 29, 2016	
Effective Date:	Reference current copy of certificate (available upon request)	
Expiry Date:	Reference current copy of certificate (available upon request)	
510(k) numbers:	Reference Appendix A	

Part 6 / Quality Planning and Objectives	
Evidence of roles & responsibilities:	Per POLICY-00001, *Cantel Quality Manual*, the Management Representative or designee has the authority and responsibility for implementation and maintenance of all Quality System elements.
Quality Objectives/Strategy:	Objectives are set at all the levels and functions in the organization to result in continuous improvement, safety and effectiveness.
Management Review:	The integrity, suitability, adequacy and effectiveness of the Quality Management System is maintained through regular management reviews. These are held once per calendar year at a minimum.
Internal audits:	Per *Cantel Corporate Internal Audit Procedure*, Crosstex conducts internal audits per an audit schedule based on the importance of the activity to be audited. The selection of auditors and conduct of audits will ensure objectivity and impartiality of the audit process. Auditors do not audit their own work. The audit results are communicated and used as an input to the management review process.

Part 7 / Order Review	
Order review process:	All orders are reviewed and documented for product requirements and to determine if the organization has the capability to deliver the product required. When orders are accepted, a review is conducted to ensure that all requirements are adequately defined and documented. All changes relating to the product requirements will be informed by the concerned personnel of changes.
Customer feedback:	Customer requirements are measured using customer feedback. The information on customer satisfaction shall be used as one of the measurements of the performance of the Quality Management System and reported to top management through the management review process.
How to place orders/obtain order status information:	Contact Customer Service via email: productorders@crosstex.com or via phone: 800-860-1888.
Special Requests:	Crosstex primarily manufactures and sells standard catalog items. Crosstex can accommodate some special requests for custom product configurations or private labeling. Please contact Customer Service to speak with a representative about such requests.

Part 8 / Training System	
Training responsibilities:	Per *Training Procedure, CSOP 013*, Management and Supervisors are responsible for documenting the training requirements for their functional group and ensuring that training is conducted and effective.
Assessment of training:	Training assessment is performed through on-the-job monitoring by Management and Supervisors and documented on employee training records.
Temporary Employee Training:	Temporary employees are subject to the same training requirements as full-time staffing.

Part 9 / Control of Documents and Records	
Change Control System:	All the documents relevant to the requirements of ISO 13485 and FDA QSR are controlled, reviewed, updated and approved by authorized personnel. Typical documents controlled are as follows: drawings, specifications, device master records, technical files, design history files, national and international regulatory standards, Quality Manual, procedures, instructions and forms.
Issuance of new revisions and removal of obsolete documents:	Documents created or changed follow the current document control procedure, tracking and controlling the distribution of applicable documents to ensure that relevant versions are available at point of use.
Document distribution, maintenance, and availability at point of use:	QA is responsible to ensure current controlled documents are distributed to the appropriate department manager. Copies of the document are given to appropriate departments. It is the department manager's responsibility to ensure that only the current revisions are in the appropriate Controlled binders or in circulation.
Record retention:	All records require a retention period as described in SOP-00002, *Cantel Document & Records Control*. Records are to be maintained for at least the lifetime of the device, or as directed by applicable regulatory requirements, but not less than two years from the medical device release.
Storage of Quality System Records:	Non-Electronic records and applicable product documents are stored in file cabinets, office areas, or similar protected environments away from extreme heat, moisture, and/or other adverse environmental conditions that would damage or destroy these items. Electronic records and applicable product documents are stored in the appropriate folders maintained by the responsible department. Additionally, electronic records are backed up to prevent data loss should a malfunction occur.
Control of client specifications:	Off-the-shelf product must comply with Crosstex's specifications prior to distribution. When applicable, client-specific requirements are documented in the Device History Record (DHR) and then reviewed by QA prior to distribution.
Document control for client documents:	These are monitored and controlled per CSOP 015, *Good Documentation Practices for Keeping Quality Records*. Quality records are stored in secure locations with limited access and scanned/stored electronically. Data back-up is performed nightly per CSOP 039, *Computer Back-Up by IT department.*
Review of client specifications:	Performed during new product initiation as dictated by ECO procedures, and communicated for each order through ERP document generation (sales orders, packing lists).
Electronic systems:	Sage/MAS 500

Part 10 / Purchasing and Raw Material Control	
Method for selecting vendors:	Per SOP-00007, *Cantel Purchasing Controls*, suppliers are selected and/or evaluated based upon their ability to meet product requirements and specifications.
Purchases are only made from approved suppliers:	A list of acceptable suppliers (vendors) is maintained and controlled and constitutes an Approved Vendor List (AVL).
Access to stock rooms and material areas:	Limited to personnel working within these areas.
Acceptance activities:	Per SSOP 003, *Receiving, Inspection and Acceptance of Incoming and In-house Manufactured Goods/Materials,* all raw materials and products received are subject to verification at receiving or incoming inspection against the purchase order requirements and purchase specification, where applicable. Records of verification of products are maintained.
Nonconforming material:	Per CSOP 003, *Control of Nonconforming Products or Materials,* records of the nature of the non-conformity and subsequent action taken, including concessions obtained, shall be maintained. Per SOP-00007, *Cantel Purchasing Controls*, non-fulfillment of purchasing requirements are addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.
Business Continuity Plan	There is no formal general plan in place. We have back-up suppliers for as many materials as possible.
Pallets:	Heat treated and stored in clearly marked areas away from product.

Part 11 / Manufacturing, Traceability and Packaging	
Manufacturing process overview:	Based on inventory levels or special orders, a decision is made to start production. Work orders are created through the ERP system and delivered to Supervisors and Leads for manufacturing scheduling. First article inspection is performed by Quality Control associates, with additional sampling performed in-process as required by Production SOPs and QA SOP 003, *Quality Assurance Monitoring of Production Product*. DHR review is performed upon job completion by Quality Assurance and final product is accepted via communication to Inventory Control and visually controlled/segregated by physical labeling systems.
Line clearance and cleaning procedures:	Before beginning any task relating to product manufacturing or packaging the area must be clear of debris and other product prior to starting the task to prevent product mix-up. The area should be cleaned using a departmental, equipment or specific-to-the-area cleaning procedure.
Gowning requirements:	LSOP 094, *Laboratory Production Gowning*, describes the procedures for specific gowning methods employed to maintain sanitary environmental conditions and personal protection in the various production and packaging areas during manufacturing activities.
Traceability:	Traceability of product is controlled per the lot numbering system and associated DHR documentation; Shipping/Receiving Form, Inspection Checklist, Production Log, Packaging Log, and Inventory Control Records.
Acceptance status:	Product accepted per defined Inspection Checklist and/or Finish Specification acceptance criteria. Acceptance documentation is retained as part of the DHR. Accepted product is assigned a unique designation within MAS 500, physically segregated from WIP or unaccepted product, and labeled by QA with an acceptance sticker.
Device History Records	Maintained and controlled per QA SOP 002, *Device Master Record/Device History Record*

Part 11 / Manufacturing, Traceability and Packaging			
Critical products characteristics:	For Biological Indicators:	• Resistance characteristics, such as D-value, survival/kill windows, z-value (if applicable)	• Population • Purity
	For Growth Promotion Suspensions:	• ≤ 100 Colony Forming Units • Purity	• ≤ 5 Passages
	For Chemical Indicator products:	• Initial color • Physical appearance requirements	• Signal color when exposed to specified conditions
	For Chemical Indicating Ink products:	• Initial color • Signal color when exposed to specified conditions	• pH • Viscosity
Capacity tracking:	We do not utilize a formal capacity tracking system at this time; however, we understand our capacity limitations based on available current resources (e.g.: equipment, human, materials, space allocations). Capacity issues are continuously managed, as well as realistic promise dates are communicated to our clients.		
Handling and storage conditions:	Handling, storage and shipping conditions are considered and determined during the product development process as a requirement of Design Controls, per ISO 13485 and 21 CFR Part 820. Crosstex's past experience with similar product configurations is used as a starting point during product development. Planned conditions are tested during product verification/validation studies.		
Off-site storage:	Utilized as needed through an approved vendor. Product stored off-site is subject to environmental controls for temperature and humidity.		
Inspection and testing:	Acceptance activities are performed on incoming raw materials, according to defined requirements outlined in the purchase order requirements and purchase specifications, where applicable. In-process inspections/tests are performed according to work instructions. Final inspection occurs on each lot according to finish good specifications, prior to QA review and approval. Results are documented on Inspection Checklists and or Finish Specifications and retained with the DHR.		
Retained samples:	Stored under environmental controls for temperature and humidity for 5 years beyond the life of the product.		
Acceptance status:	Per QASOP 003, *Quality Assurance Monitoring of Production Product*, the batch/trace records are reviewed, verified and approved for release by Quality. Status identification of product is maintained throughout production and storage to ensure that the product has passed the necessary required inspection/tests before it is released. Evidence of conformity with acceptance criteria is maintained in the records. The records indicate the person authorizing release of the product. For our CPI-xxx and SP-xxx product lines, we use the procedure SOP_00316, *Inspection and Packaging of Chemical Process Indicators*.		
Shipments:	Each container is labeled, at a minimum, with the Product Code, Lot Number, and Quantity. A Certificate of Analysis or Certificate of Conformance is included in every shipment.		
On-time delivery tracking:	All product deliveries are tracked for Original Promise Date. This metric is included in Crosstex's Quality Index and is regularly reviewed during annual management review meetings as well as bi-monthly Customer Review meetings.		
Distribution traceability:	Distributed product is traceable through MAS 500.		

Part 11 / Manufacturing, Traceability and Packaging	
Sub-contractors:	For many of our CPIs, Indicating Inks are manufactured in Crosstex's Rush, NY facility, then sent to a subcontractor for application to the substrate, slitting and die cutting. Crosstex has continued our relationship with the subcontractor and has also validated the application of the Ink to the substrate (for all processes except radiation CPIs), slitting and die cutting within our Rush, NY facility. The final product, when manufactured in conjunction with the subcontractor or internally, is evaluated by Crosstex to ensure compliance with the specifications and ISO 11140-1. Some of our CPIs are manufactured in-house using a combination of inks manufactured and validated on-site, as well as purchased inks from an outside approved vendor. Slitting and die cutting are performed within the Rush, NY facility, and all release testing of these Crosstex CPIs is performed on-site using state of the art laboratory equipment. Final product is evaluated by Quality Assurance to ensure compliance with the specifications and ISO 11140-1. Sourced CPIs are purchased through vendors that have undergone the Crosstex Supplier Selection and Evaluation process. All sourced products are received with a certificate of compliance and are subject to the same release criteria witnessed with the in-house manufactured CPIs.

Biological Indicators Lot Numbering System

Product Type	Organism	Lot Number Designation
6 mm Paper Discs	*Bacillus atrophaeus*	NDxx[1]
	Geobacillus stearothermophilus	SDxx[1]
3 mm Paper Discs	*Bacillus atrophaeus*	xxxxx-xx
	Geobacillus stearothermophilus	xxxxx-xx
Strips	*Bacillus atrophaeus*	RAxx[1]
	Geobacillus stearothermophilus	RUxx[1]
	Bacillus pumilus	Pxx[1]
	Bacillus subtilis Cell Line 5230	Bxxx[1]
	Dual Species	Dxx[1]
Suspensions	*Bacillus atrophaeus*	BTxxx[1]
	Bacillus pumilus	PUxxx[1]
	Bacillus subtilis Cell Line 5230	Usxxx[1]
	Bacillus subtilis Cell Line 6633	SBxxx[1]
	Geobacillus stearothermophilus	ARxxx[1]
Traditional (Large) SCBIs	Any	Lxxxx[1]
SporView® SCBIs	Any	xxxx
Spore ampoules	*Geobacillus stearothermophilus*	Sxxxxxxx
Threads, Steel Wires, Steel Coupons, Steel Discs	Any	xxxxx-xx

[1]where x designates sequential numbering sequence e.g., D45, D46, D47, etc.

Part 11 / Manufacturing, Traceability and Packaging

Chemical Indicators Lot Numbering System			
Product Type	Sterilization	Lot Number Designation	
Chemical Process Indicators	Steam	YYMMxxx	Where MM is the month of manufacture, YY is the year of manufacture, and xxx is a numerical sequencing representative of the order in which batches were manufactured.
	Hydrogen Peroxide	YYMM	
	Ethylene Oxide	YYMM	
	Dry Heat	YYMM	

Chemical Indicators Lot numbering System			
Product Type	Sterilization	Lot Number Designation	
Chemical Process Indicators (Product codes CPI-Xxx or SP-Xxx)	Radiation	YY**R**MMDD-xx	Where *YY* is the year of manufacture, *MM* is month of manufacture, *DD* is day of manufacture (specifically, the date the ink is applied to the substrate), and *xx* is a sequential number representing each unique lot of ink applied in a given day.
	Steam	YY**S**MMDD-xx	
	Hydrogen Peroxide	YY**P**MMDD-xx	
	Ethylene Oxide	YY**E**MMDD-xx	
	Dry Heat	YY**DH**MMDD-xx	
	Depyrogenation	YY**DP**MMDD-xx	

Part 12 / Corrective and Preventive Action/Complaints	
Nonconforming Product and Corrective Actions:	Per CSOP 016, *Corrective Action (CAPA)*, products which do not conform to requirements are identified and controlled to prevent their unintended use or delivery. The controls and related responsibilities and authorities for dealing with non-conforming product are defined in a documented procedure. Non-conforming product is dealt with in one or more of the following ways: • By taking action to eliminate the detected non-conformity. • By authorizing its use, release or acceptance under concession. • By taking action to preclude its distribution.
Preventive Actions:	A documented procedure is established to define requirements for: • Determining the potential non-conformities and their causes. • Evaluating the need for action to prevent occurrence of non-conformities. • Determining and implementing the preventive action needed. • Records of the result of the action taken. • Reviewing of preventive action taken and its effectiveness.
Rework:	Per CSOP 003, *Control of Nonconforming Products or Materials*, when a non-conforming product is corrected or reworked, it is to be subjected to re-verification to demonstrate conformity to the requirements.
Complaints:	Per CSOP 031, *Complaint Inquiry Handling*, a documented process is utilized for receiving, recording, and analyzing customer complaints on products. Personnel are trained to collect and coordinate all written and/or customer complaints. The complaint process includes the following: • Establishing responsibility for operating the system. • Evaluating the complaint. • Creating records and summaries to enable the major causes of complaints to be determined. • Taking corrective action.

Part 12 / Corrective and Preventive Action/Complaints	
	• Segregating and disposing of customer returns. • Maintaining records of customer correspondence and other relevant records.
Returned material authorization (RMA):	Upon inquiry and on a case-by-case basis, customer service will initiate the RMA form out of our financial software.
Change Notification:	When required by a Quality Agreement or Regulatory request, Crosstex communicates changes that would result in significant changes to the customer requirements.
Product recall, market correction and removal:	Crosstex has in place documented processes for issuing Advisory Notices and/or recall information to national, international and regional regulatory agencies, if notification of adverse events that meet specified reporting criteria are required.

Part 13 / Environmental Controls	
Environmental controls:	Per CSOP 030, *Environmental Control*, temperature and humidity are monitored in the Ink Storage Room, Ink Manufacturing Room, Light Manufacturing, Packaging Warehouse, Portable Cleanroom, Production Area, Shipping, SSI Room, Testing Lab, Production Storage Refrigerators, and R&D office. Acceptable ranges for temperature are 15-30°C, with a target of 20-25°C for employee comfort. Humidity ranges for all Biological Indicators are 20-70%, chemical indicators have an acceptable range of 30-70% with some chemical indicator products having an acceptable range of 20-70%. Any recording not found within range is reported to management immediately. All environmental monitoring devices used to monitor the areas described above are calibrated and traceable to N.I.S.T. standards or equivalent.
Pest Control:	Per CSOP 030, *Environmental Control*, a contractor's technician is scheduled to service the facility monthly. The technician inspects glue boards and replaces as deemed necessary. The technician also reviews the Pest Activity Sighting Log. A pest sighting will be documented on the Pest Activity Sighting Log. If pests are noted within the facility or around the building, management is notified. Management will assess the need to contact the pest control service for an unscheduled visit.
Water filtration system:	Water For Injection (WFI) is commercially purchased for use in our water-based suspensions. An Elga PURELAB® flex 2 distilled water dispenser is installed for water used in the manufacture of inks. Functionality is monitored and documented daily.
Disaster Preparedness Plans:	Sister sites contain like-for-like equipment for the majority of our operations. Approved vendors may be utilized for sourcing of materials if needed.

Part 14 / Analysis of Data	
Sampling:	For BIs: Random sampling representative of entire production run with samples subject to full survival/kill testing and D-value testing. For CIs: First article inspection followed by sampling every 30 – 60 minutes throughout the production run (for those made in-house), and final article inspection (for those made in-house and by subcontractors).
Trending:	Nonconformance trending and customer complaint trending are captured on a monthly basis and ultimately reported during annual Management Review.
Validation program:	Per CSOP 019, *Production and Process Controls*, major changes to a process that could impact the final results shall be verified and validated before implementation of the change according to change process and validation procedure. Assessment of change is documented through a business analysis and pFMEA/Risk Assessment per procedures for Engineering Change Orders/Requests. The results of testing shall be documented to substantiate any changes.

Part 14 / Analysis of Data	
Risk management:	CSOP 011a, *Risk Management*, specifies a process for Crosstex at both the Rush, NY, and Cuba, NY, locations to identify the hazards associated with medical devices, to estimate and evaluate the associated risks, to control these risks and to monitor effectiveness of the controls. This process may also be used to update existing product/product line risk management plans.

Part 15 / Equipment Maintenance		
Major Manufacturing Equipment:	Flexographic Presses	Finishing Equipment
	Automated Inoculator / Packager	Vial Filling / Sealing Equipment
	Sterilizers and Resistometers	Incubators
	Refrigerators	Pipettes
Inspection and Measuring Equipment:	Spectrodensitometer	
Test/measuring equipment:	Crosstex has established procedures for control of inspection, measurement, and test equipment used to determine specifications or verifying conformance of materials or products to the established specifications. All devices used to measure, gauge, test, inspect or otherwise examine products to determine compliance with specifications must be verified or calibrated with calibration standards traceable to national or international measurement standards.	
Preventive maintenance and calibration:	Per CSOP 010, *Inspection Measuring and Test Equipment*, the equipment manufacturer is consulted for frequency requirements on preventive maintenance. For maintained equipment items, the frequency is listed in the Equipment Listing and usually coincides with the Inspection/Calibrations schedule. Each calibration and inspection shall have an SOP and/or QC form which tracks the calibration/inspection history of the equipment. Calibrations and inspections shall be performed by trained personnel. When contracting a third party to perform equipment calibration and/or inspection, the results shall be traceable and a Calibration Certificate required.	

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Appendix A	
510(k) Device Listings	
K020409	SPSmedical STEAM*Plus*™ Sterilizer Test Pack
K022706	SPSmedical SporView® Steam BI Test Pack
K023716	SPSmedical SporView® Bacterial Spore Strip for steam (reduced incubation time)
K030680	SPSmedical Gas Plasma Chemical Indicators (Yellow/Blue or Red/Blue)
K041017	SPSmedical Air View™ Bowie-Dick Test Pack and Air View™ Bowie-Dick Indicator Sheets (daily testing as described in AAMI/ANSI ST-46)
K041099	SporView® BI strip for chemical vapor (reduced incubation time)
K043135	SporView® PA Culture Set
K051173	SporView® Plus Steam BI Test Pack
K063799	SPSmedical STEAM*Plus*™ Steam Integrator
K070595	SporView® Steam Self-Contained Steam Biological Indicator
K081879	SporView® PA Culture Set (reduced incubation time of 16 hours)
K090650	SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators
K102363	SPSmedical EM*Plus*™ 270F Steam Emulator
K110152	SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators (additional use in Steris V-Pro® maX flexible sterilization cycle)
K111515	SporView® Steam Self-Contained Steam BI (additional sterilization temperature of 135°C)
K122024	SporView® 10 Self-Contained Steam Biological Indicator (reduced incubation time)
K130211	SPSmedical Air View™ Bowie-Dick Test Pack and Air View™ Bowie-Dick Indicator Sheets (daily testing as described in AAMI/ANSI ST79)
K132291	NAMSA Chemical Process Indicator Strip for Steam
K133204	Air View™ II Bowie-Dick Test Pack (ISO 11140-5)
K140566	SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators (additional use of Sterilucent™ PSD-85 Lumen and Non-lumen cycles)
K140620	SporView® Plus Steam BI Test Pack
K143520	SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators (additional use in Steris V-Pro® 60)
K882756	Lantor Cube Sterilizer Test Pack
K890754	SporView® Culture Media
K890755	Steam Sterilization Indicator Tape
K890757	C-Vapor Sterilization Indicator, Chemical Vapor
K890758	Dry Heat Sterilization Indicator Tape
K890759	Strip, Sterilization Indicator; Steam
K890760	EO Gas Chemical Indicator Strips
K890761	Dry Heat Chemical Indicator
K890763	Dual Steam / EO Gas Chemical Indicator Labels
K890764	Label, Sterilization Indicator; Radiation
K890765	Strip, Sterilization Indicator; Steam or EO Gas
K905425	SporView® Single and Dual Species BI Strips
K931202	Sterilization Wrap-Sterisheet