DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 17, 2017

Cook Incorporated
Kotei Aoki
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K160200
Trade/Device Name: Melker Cuffed Emergency Cricothyrotomy Catheter Set - Percutaneous, Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical, Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set
Regulation Number: 21 CFR 868.5090
Regulation Name: Emergency Airway Needle
Regulatory Class: II
Product Code: BWC, OGP, JOH
Dated: January 13, 2017
Received: January 17, 2017

Dear Kotei Aoki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160200

Device Name
Melker Cuffed Emergency Cricothyrotomy Catheter Set - Percutaneous
Melker Cuffed Emergency Cricothyrotomy Catheter Set - Surgical
Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set

Indications for Use *(Describe)*
The Melker Cuffed Emergency Cricothyrotomy Catheter Set - Percutaneous is intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing the percutaneous entry (Seldinger) technique via the cricothyroid membrane.

The Melker Cuffed Emergency Cricothyrotomy Catheter Set - Surgical is intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing the surgical technique via the cricothyroid membrane.

The Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set is intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing either the percutaneous entry (Seldinger) technique or the surgical technique via the cricothyroid membrane.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Melker Cuffed Emergency Cricothyrotomy Catheter Set - Percutaneous
Melker Cuffed Emergency Cricothyrotomy Catheter Set - Surgical
Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set
21 CFR §868.5090
Date Prepared: 15 February 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Kotei Aoki
Applicant Address:	750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x102630
Contact Fax Number:	(812) 332-0281

Device Information

Trade Name:	**Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous** **Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical** **Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set**
Common Name:	Emergency airway needle
Classification Name:	Emergency airway needle; BWC (21 CFR §868.5090) Cricothyrotomy Kit; OGP Tracheostomy tube and tube cuff; JOH

Predicate Device:

- K010016, Melker Cuffed Emergency Cricothyrotomy Catheter

Device Description:

The Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous, Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical, and the Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set consist of an airway catheter, a loading dilator, a wire guide, a catheter needle, and an introducer needle. In addition to these components, standard preparation components, such as a syringe, scalpel, dilator forceps, gauze, drape, tracheostomy tape, and tracheal hook are included. The sets consist of any combination of components appropriate for either percutaneous or surgical placement of a cricothyrotomy tube, or both.

The curved cricothyrotomy catheter is manufactured as a 22 French catheter with a length of 9 centimeters and an inner diameter of 5 millimeters. The loading dilators are either 11

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centimeters or 12 centimeters long. The stainless steel wire guide has a 0.038-inch diameter and a length of 40 centimeters. The catheter needle is a two-part needle comprised of a small hubbed catheter sheath covering a hubbed needle. The sheath of the catheter needle is manufactured from fluorinated ethylene propylene tubing. The catheter needle is manufactured using an 18 gage cannula with a length of 7 centimeters. The introducer needle is also manufactured from 18 gage stainless steel and has a length of either 5 centimeters or 7 centimeters.

Intended Use:

The Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous is intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing the percutaneous entry (Seldinger) technique via the cricothyroid membrane.

The Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical is intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing the surgical technique via the cricothyroid membrane.

The Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set is intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing either the percutaneous entry (Seldinger) technique or the surgical technique via the cricothyroid membrane.

The intended uses are same as that of the predicate device, the Melker Cuffed Emergency Cricothyrotomy Catheter (K010016).

Comparison to Predicate:

The Melker Cuffed Emergency Cricothyrotomy Catheter Set –Percutaneous, Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical, and the Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set are substantially equivalent to the predicate device, the Melker Cuffed Emergency Cricothyrotomy Catheter (K010016), in that these devices have the same intended use, technological characteristics, materials of construction, and are similar in design. The subject device sets offer both percutaneous (Seldinger) and surgical techniques of establishing the airway, and contain sets of accessory components to support both surgical and percutaneous methods of performing emergency cricothyrotomy, as circumstances require.

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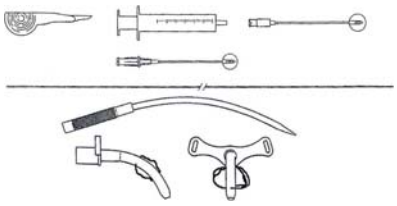
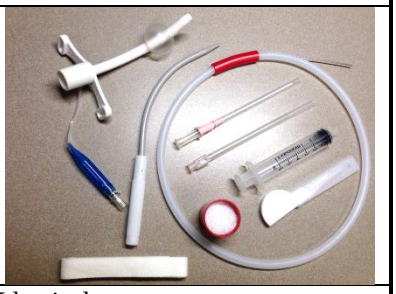
Table 1, Table 2, and Table 3 provide the detailed comparison of each subject device to the predicate device.

Table 1 Substantial Equivalence Comparison Chart for Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous

	Predicate Device **Melker Cuffed Emergency Cricothyrotomy Catheter K010016**	Subject Device **Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous**
Regulation Number **Product Code**	1) 21 CFR §868.5090 BWC 2) 21 CFR §868.5800 JOH	1) 21 CFR §868.5090 BWC 2) 21 CFR §868.5800 OGP 3) 21 CFR §868.5800 JOH
Classification Name	1) Emergency airway needle 2) Tracheostomy tube and tube cuff	Identical
Class	II	Identical
Intended Use	Used for emergency airway access when endotracheal intubation cannot be performed	Intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing the percutaneous entry (Seldinger) technique via the cricothyroid membrane.[1]
Product Illustrations		
Method of airway access	Percutaneous	Identical

[1] Both the subject device and the predicate device establish the airway by the percutaneous access. The subject device specifies the access method clearly.

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Table 1 Substantial Equivalence Comparison Chart for Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous (Continued)

		Predicate Device	Subject Device
		Melker Cuffed Emergency Cricothyrotomy Catheter K010016	**Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous**
Airway Catheter	**Material**	Polyvinylchloride with Polyethylene Cuff	Identical
	Inner Diameter	5 mm	Identical
	Outer Diameter	22 French	Identical
	Length	8 cm	9 cm[2]
Loading Dilator	**Material**	Polyvinylchloride	Identical
	Outer Diameter	14 French	Identical
	Length	14 cm	12 cm[2]
	Tip Shape	Tapered	Identical
Wire Guide	**Material**	Stainless Steel	Identical
	Diameter	0.038 in	Identical
	Length	40 cm	Identical
Catheter Needle (if applicable)	**Catheter Material**	Fluorinated Ethylene Propylene	Identical
	Needle Material	Stainless Steel	Identical
	Gage	18 gage	Identical
	Length	7 cm	Identical
Introducer Needle (if applicable)	**Hub Material**	Polycarbonate	Identical
	Needle Material	Stainless Steel	Identical
	Gage	18 gage	Identical
	Length	7 cm	5, 7 cm[2]
	Needle Coating	Silicone	Identical
Accessory Components		Syringe, Scalpel	Syringe, Scalpel, Tracheostomy Tape[3]
MR Compatibility		Not indicated	MR Conditional[4]
Packaging		Tyvek/polyethylene film pouch	Identical
Sterilization		EtO	Identical

[2] The dimensional variations are within the tolerances on the specifications of the predicate device. Furthermore, the materials of construction in the respective components are identical.

[3] The Tracheostomy Tape is a legally marketed component and is an accessory for use with cricothyrotomy procedures.

[4] MR testing was not previously done for the predicate device and has been performed, as per FDA Guidance, *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*. Testing to support the MR Conditional status for this device has been provided.

In conclusion, the differences noted in the table above do not raise different questions of safety or effectiveness of the subject device, as compared to the predicate device.

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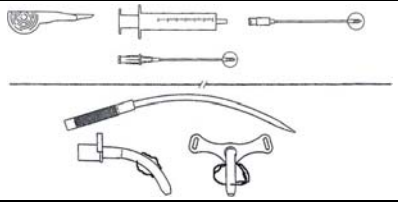
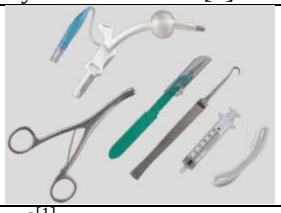
Table 2 Substantial Equivalence Comparison Chart for Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical

	Predicate Device	**Subject Device**
	Melker Cuffed Emergency Cricothyrotomy Catheter K010016	**Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical**
Regulation Number **Product Code**	1) 21 CFR §868.5090 BWC 2) 21 CFR §868.5800 JOH	1) 21 CFR §868.5090 BWC 2) 21 CFR §868.5800 OGP 3) 21 CFR §868.5800 JOH
Classification Name	1) Emergency airway needle 2) Tracheostomy tube and tube cuff	Identical
Class	II	Identical
Intended Use	Used for emergency airway access when endotracheal intubation cannot be performed	Intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing the surgical technique via the cricothyroid membrane.[1]
Product Illustrations		
Method of airway access	Percutaneous	Surgical[1]

[1] The subject device establishes the airway by the surgical access. The appropriate accessory components are provided with the subject device to establish the airway surgically. The Airway Catheter and the Loading Dilator, used in the surgical access, function in the same manner as those used in the percutaneous access. The Airway Catheter is as capable of being placed via the surgical access as via the percutaneous access.

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Table 2 Substantial Equivalence Comparison Chart for Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical (Continued)

		Predicate Device	Subject Device
		Melker Cuffed Emergency Cricothyrotomy Catheter K010016	**Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical**
Airway catheter	**Material**	Polyvinylchloride with Polyethylene Cuff	Identical
	Inner Diameter	5 mm	Identical
	Outer Diameter	22 French	Identical
	Length	8 cm	9 cm[2]
Loading dilator	**Material**	Polyvinylchloride	Identical
	Outer Diameter	14 French	Identical
	Length	14 cm	11 cm[2]
	Tip Shape	Tapered	Blunt[3]
Wire Guide	**Material**	Stainless Steel	N/A
	Diameter	0.038 in	N/A
	Length	40 cm	N/A
Catheter Needle (if applicable)	**Catheter Material**	Fluorinated Ethylene Propylene	N/A
	Needle Material	Stainless Steel	N/A
	Gage	18 gage	N/A
	Length	7 cm	N/A
Introducer Needle (if applicable)	**Hub Material**	Polycarbonate	N/A
	Needle Material	Stainless Steel	N/A
	Gage	18 gage	N/A
	Length	7 cm	N/A
	Needle Coating	Silicone	N/A
Accessory Components		Syringe, Scalpel	Syringe, Scalpel, Tracheostomy Tape, Tracheal Hook, Dilator Forceps[4]
MR Compatibility		Not indicated	MR Conditional[5]
Packaging		Tyvek/polyethylene film pouch	Identical
Sterilization		EtO	Identical

[2] The dimensional variations are within the specifications of the predicate device. Furthermore, the materials of construction in the respective components are identical.

[3] As the surgical access to the airway does not utilize the wire guide, it also does not require a tapered Loading Dilator. The dilator tip is left blunt to help mitigate the risk of perforating the posterior tracheal wall (in the percutaneous access, the same risk is mitigated as the wire guide diverts the protruding tapered dilator tip).

[4] The Tracheostomy Tape, the Tracheal Hook, and the Dilator Forceps are all legally marketed components and are accessories for use with the cricothyrotomy procedures using the surgical access.

[5] MR testing was not previously done for the predicate device and has been performed, as per FDA Guidance, *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*. Testing to support the MR Conditional status for this device has been provided.

In conclusion, the differences noted in the table above do not raise different questions of safety or effectiveness of the subject device, as compared to the predicate device.

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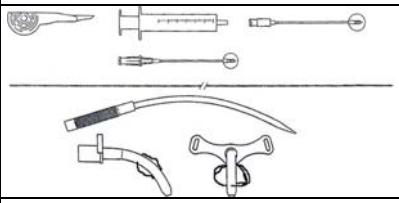
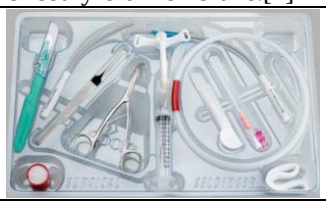
Table 3 Substantial Equivalence Comparison Chart for Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set

	Predicate Device	Subject Device
	Melker Cuffed Emergency Cricothyrotomy Catheter K010016	**Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set**
Regulation Number **Product Code**	1) 21 CFR §868.5090 BWC 2) 21 CFR §868.5800 JOH	1) 21 CFR §868.5090 BWC 2) 21 CFR §868.5800 OGP 3) 21 CFR §868.5800 JOH
Classification Name	1) Emergency airway needle 2) Tracheostomy tube and tube cuff	Identical
Class	II	Identical
Intended Use	Used for emergency airway access when endotracheal intubation cannot be performed	Intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing either the percutaneous entry (Seldinger) technique or the surgical technique via the cricothyroid membrane.[1]
Product Illustrations		
Method of airway access	Percutaneous	Percutaneous, Surgical[1]

[1] Both the subject device and the predicate device establish the airway by the percutaneous access. The subject device also allows for the surgical method of establishing the airway. The appropriate accessory components are provided with the subject device to establish the airway both percutaneously and surgically. The Airway Catheter and the Loading Dilator, used in the surgical access, function in the same manner as those used in the percutaneous access. The Airway Catheter is as capable of being placed via the surgical access as via the percutaneous access. Each Loading Dilator is easily identified by the tip shape.

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Table 3 Substantial Equivalence Comparison Chart for Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set (Continued)

		Predicate Device	Subject Device
		Melker Cuffed Emergency Cricothyrotomy Catheter K010016	**Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set**
Airway catheter	**Material**	Polyvinylchloride with Polyethylene Cuff	Identical
	Inner Diameter	5 mm	Identical
	Outer Diameter	22 French	Identical
	Length	8 cm	9 cm[2]
Loading dilator	**Material**	Polyvinylchloride	Identical
	Outer Diameter	14 French	Identical
	Length	14 cm	11, 12 cm[2]
	Tip Shape	Tapered	Tapered, Blunt[3]
Wire Guide	**Material**	Stainless Steel	Identical
	Diameter	0.038 in	Identical
	Length	40 cm	Identical
Catheter Needle	**Catheter Material**	Fluorinated Ethylene Propylene	Identical
	Needle Material	Stainless Steel	Identical
	Gage	18 gage	Identical
	Length	7 cm	Identical
Introducer Needle	**Hub Material**	Polycarbonate	Identical
	Needle Material	Stainless Steel	Identical
	Gage	18 gage	Identical
	Length	7 cm	Identical
	Needle Coating	Silicone	Identical
Accessory Components		Syringe, Scalpel	Syringe, Scalpel, Tracheostomy Tape, Tracheal Hook, Dilator Forceps, Gauze, Drape[4]
MR Compatibility		Not indicated	MR Conditional[5]
Packaging		Tyvek/polyethylene film pouch	Identical
Sterilization		EtO	Identical

[2] The dimensional variations are within the specifications of the predicate device. Furthermore, the materials of construction in the respective components are identical.

[3] As the subject device allows both the percutaneous access and the surgical access to the airway, it provides all the appropriate accessory components required for both methods of airway access. Therefore, the subject device provides both the tapered tip dilator and the blunt tip dilator.

[4] The Tracheostomy Tape, the Tracheal Hook, the Dilator Forceps, the Gauze, and the Drape are all legally marketed components and are accessories for use with the cricothyrotomy procedures using either method of airway access.

[5] MR testing was not previously done for the predicate device and has been performed, as per FDA Guidance, *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*. Testing to support the MR Conditional status for this device has been provided.

In conclusion, the differences noted in the table above do not raise different questions of safety or effectiveness of the subject device, as compared to the predicate device.

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Technological Characteristics:

The following tests have been conducted to ensure reliable design and performance under the specified design requirements. These tests include:

- Evaluation of Durability of the Cuff (Zero-Time, Three-Year Accelerated Aging) – The acceptance criterion was that the cuff must remain fully intact and without any leaks following insertion. The predetermined acceptance criterion was met.
- Tensile Test of the Shaft of the Dilator (Three-Year Real-Time) – The acceptance criterion was that the dilator shaft must withstand a minimum force at break of 15 N. The predetermined acceptance criterion was met.
- Magnetically Induced Displacement Force – Per ASTM F2052, the displacement force shall be less than or equal to the worst case displacement force due to the earth's gravity. The predetermined acceptance criterion was met.
- Magnetically Induced Torque – Per ASTM F2213, the magnetically induced torque shall be less than or equal to the worst case torque due to earth's gravity. The predetermined acceptance criterion was met.
- Radiofrequency Induced Heating – The electrical conductivity of the Melker Emergency Cricothyromtomy Catheter must be < 1 S/m. The predetermined acceptance criterion was met.
- Magnetic Resonance Image Artifact – Image artifact was assessed according to ASTM F2119.

The results of these tests provide reasonable assurance that the device is as safe and effective as the predicate device for its intended use.

Conclusion:

The results of these tests support a conclusion that the subject devices, Melker Cuffed Emergency Cricothyrotomy Catheter Set –Percutaneous, Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical, and the Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set, met the design input requirements based on the intended use and support the conclusion that these devices do not raise different questions of safety or effectiveness as compared to the predicate device. Therefore, the subject devices are substantially equivalent to the predicate device, the Melker Cuffed Emergency Cricothyrotomy Catheter (Cook Incorporated, K010016).