October 30, 2020

VBM Medizintechnik GmbH
Jannika Jaeger
Regulatory Affairs Manager
Einsteinstrasse 1
Sulz am Neckar, 72172 De

Re: K200190
Trade/Device Name: ScalpelCric
Regulation Number: 21 CFR 868.5090
Regulation Name: Emergency Airway Needle

Regulatory Class: Class II
Product Code: BWC, JOH, OGP
Dated: September 25, 2020
Received: September 28, 2020

Dear Jannika Jaeger:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200190

Device Name

ScalpelCric
Crycothyrotomy set - Scalpel technique

Indications for Use *(Describe)*

Emergency airway access via the cricothyroid membrane. Life-threatening dyspnoea that cannot be controlled in any other way.

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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K200190

VOLUME 003

510(k) Summary

DATE OF APPLICATION: 10/26/2020

APPLICANT:

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1 Device Name

Trade Name:	*ScalpelCric*
Common Name:	*Cricothyrotomy Set*
Device Classification Name:	*Needle, Emergency Airway* *Cricothyrotomy Kit* *Tube tracheostomy and tube cuff*

2 Classification / Product Code

ScalpelCric can be classified according to following device name and product code:

Primary Product Code

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Needle, Emergency Airway	Emergency airway needle.	Anesthesiology	Anesthesiology	BWC	868.5090	2

Additional Product ode

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Tube tracheostomy and tube cuff	Tracheostomy tube and tube cuff.	Anesthesiology	Anesthesiology	JOH	868.5800	2

3 Predicate Device / Reference Device

Device	Predicate Device	Reference Device	510(k) Number	510(k) Holder
Needle, Emergency Airway	Melker Cuffed Emergency Cricothyrotomy Catheter Set -Percutaneous, Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical, Melker Universal Cuffed Emergency Cricothyrotomy Catheter Set	---	K160200	COOK INCORPORATED 750 DANIELS WAY Bloomington, Indiana 47404
	---	Airway Connector with Flex Tube	K942392	Covidien Llc formerly MALLINCKRODT DAR S.R.L. 15 HAMPSHIRE STREET

				Mansfield, MA US 02048

4 Device Description

Surgical Cricothyrotomy set for securing the airway in case of upper airway obstruction, respectively as “Ultima Ratio” if all other attempts to ventilate the patient failed.

The set consists of scalpel, bougie, tube, extension tube with swivel connector, syringe and necktape.

5 Intended Use

Surgical cricothyrotomy set for securing the airway in case of upper airway obstruction or as ultima ratio if all other attempts to ventilate the patient have failed. ScalpelCric can be used with resuscitation bags or other standard ventilation systems.

Clinical benefit: ScalpelCric allows the ventilation of patients as ultima ratio.

Patient target group: Adults

Location of use: Hospital and pre-hospital conditions including military use

6 Indication for Use

Emergency airway access via the cricothyroid membrane. Life-threatening dyspnoea that cannot be controlled in any other way.

7 Mechanism of Action

The device is used for securing the airway in case of upper airway obstruction. After incision of the cricothyroid membrane a bougie is inserted to allow an easy insertion of the tube over the bougie into the trachea. After bougie removal, inflation of the cuff and fixation of the tube the patient can be ventilated.

8 Technological Characteristics

The technological characteristics of ScalpelCric are substantially equivalent to the technological characteristics of the predicate device or the reference device.

8.1 Device Characteristics Table

Company	**VBM --- ScalpelCric, Cricothyrotomy Set (New Device)**	**Cook Incorporated --- Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical (Predicate Device)**	**Covidien llc --- Airway Connector with Flex Tube (Reference Device)**	**Result**
Device Name	Needle, Emergency Airway Cricothyrotomy kit Tube tracheostomy and tube cuff	Needle, Emergency Airway Cricothyrotomy kit Tube tracheostomy and tube cuff	Airway Connector with Flex Tube	-

Company		VBM --- ScalpelCric, Cricothyrotomy Set (New Device)	Cook Incorporated --- Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical (Predicate Device)	Covidien llc --- Airway Connector with Flex Tube (Reference Device)	Result
Regulation Number		868.5090 868.5800 868.5800	868.5090 868.5800 868.5800	868.5810	Substantially Equivalent[(A)]
Class		2	2	1	Substantially Equivalent[(A)]
Code		BWC OGP JOH	BWC OGP JOH	BZA	Substantially Equivalent[(A)]
510(k) number		---	K160200	K942392	-
Tube / Airway Catheter	**Inner Diameter**	6 mm	5 mm	N.A.	Substantially Equivalent[(A)]
	Outer Diameter	9 mm	22 French (7,2 mm)	N.A.	Substantially Equivalent[(A)]
	Length	10cm	9 cm	N.A.	Substantially Equivalent[(A)]
Bougie /Loading dilator	**Outer Diameter**	14 French	14 French	N.A.	Substantially Equivalent
	Length	40 cm	11 cm	N.A.	Substantially Equivalent[(A)]
	Tip Shape	Blunt	Blunt	N.A.	Substantially Equivalent
Syringe	**Volume**	10 ml	6 ml	N.A.	Substantially Equivalent[(A)]
Scalpel	**Type**	#10	#11	N.A.	Substantially Equivalent[(A)]
Necktape	**Availability**	Included	no Necktape included	N.A.	Substantially Equivalent[(A)]
Extension Tube with Swivel Connecto r	**Inner Diameter - patient side**	15 mm	no Extension Tube included	15 mm	Substantially Equivalent
	Inner Diameter - machine side	22 mm		22 mm	Substantially Equivalent
	Length extension tube	13 cm		13 cm	Substantially Equivalent

A. Differences in relevant characteristics have been separately evaluated during Substantial equivalence discussion. They do not raise new questions regarding safety and efficacy.

8.2 Summary of Technological Characteristics

The proposed devices are substantially equivalent in terms of design, operating principles and intended use and have similar technological characteristics to the predicate devices.

9 Performance Data

9.1 Sterilization and Shelf Life

ScalpelCric Set is supplied in sterile condition. EO-sterilizations is used for the sterilization of the ScalpelCric Set. ScalpelCric Set has a shelf life of 5 years.

9.2 Biocompatibility

Devices of the ScalpelCric Set were evaluated for their biological safety according to ISO 10993-1. All relevant endpoints have been considered. Tests regarding cytotoxicity, irritation, sensitization, Pyrogen, material mediated pyrogenicity and acute systemic toxicity were performed during the biological safety evaluation. All conducted tests have been successful. The evaluation shows the biological safety of the ScalpelCric Set.

9.2.1 Patient Contacting Components

Component	Type of physical Contact		Duration of Contact
	Category	Contact	
Scalpel	External Communicating device	Tissue/ Bone/ Dentine	< 24 hours
Bougie	External Communicating device	Tissue/ Bone/ Dentine	< 24 hours
Cuffed Tube	External Communicating device	Tissue/ Bone/ Dentine	< 24 hours
Extension Tube	Surface device	Mucosal membrane	< 24 hours
Neck tape	Surface device	Intact Skin	< 24 hours
Syringe	Without Patient Contact	Without Patient Contact	N. A.

9.2.2 Biocompatibility tests

Tested component	Conducted Test	Result
Scalpel	Cytotoxicity	Non-cytotoxic
	Material Mediated Pyrogenicity	No traces of material mediated pyrogenicity
	Acute Systemic Toxicity	No acute systemic toxic characteristics
	Pyrogen	Endotoxin free
Bougie	Irritation	No intracutaneous reactivity
	Sensitization	Non-sensitizer
	Cytotoxicity	Non-cytotoxic
	Material Mediated Pyrogenicity	No traces of material mediated pyrogenicity
	Acute Systemic Toxicity	No acute systemic toxic characteristics
Cuffed Tube	Cytotoxicity	Non-cytotoxic

	Material Mediated Pyrogenicity	No traces of material mediated pyrogenicity
	Acute Systemic Toxicity	No acute systemic toxic characteristics
	Sensitization	Non-sensitizer
	Irritation	No intracutaneous reactivity
	Pyrogen	Endotoxin free
Extension Tube	Cytotoxicity	Non-cytotoxic
	Irritation	No intracutaneous reactivity
	Sensitization	Non-sensitizer
	Pyrogen	Endotoxin free
	Material Mediated Pyrogenicity	No traces of material mediated pyrogenicity
	Acute Systemic Toxicity	No acute systemic toxic characteristics
Neck Tape	Cytotoxicity	Non-cytotoxic
Syringe	N.A.	N.A.

9.3 Sterilization and Shelf Life

ScalpelCric is supplied in sterile condition and intended to be single-use. Validated EO-sterilization procedure is used for sterilization. Residuals do not exceed the maximum amount defined by ISO 10993-7. The maximum shelf life of the Set is 5 years.

9.4 Bench Testing

The components of the ScalpelCric Set are extensively tested to prove the fulfillment of requirements defined during development. Tests could verify the suitability of all tested features.

Object under Test	**Features to be tested**	**Result**
Bonding Connector	Bonding between connector and tube	Passed
Bonding Inflation Line	Bonding between inflation line and tube	Passed
15mm Connector	Dimensions of 15mm Connector	Passed
Luer Pilot Balloon	Dimensions of the female luer connector in the pilot balloon	Passed
Cuff	Function of the Cuff	Passed
Scalpel	Function and design of the scalpel	Passed
Bougie	Bougie which shall fulfill all relevant specification according [DI] and [MS_Bougie].	Passed
Tube	Function and dimensions of the tube	Passed
Tube	Tube is recognizable in X-Ray images	Passed
extension Tube	Function and dimension of the extension tube	Passed
Neck Tape	Neck tape which shall fulfill all relevant specification according [DI]	Passed

	and [MS_NT] after 4 times sterilization	
Syringe	Function of the syringe	Passed
Tube with inflation line and cuff,	Function and features of the tube with attached inflation line and pilot balloon and with cuff	Passed
ScalpelCric	Biological compatibility	Passed
Material	Function and ingredient of the ScalpelCric materials	Passed
Tube and extension Tube	Oxygen resistance of Tube and Extension tube	Passed
Label	Device Label	Passed
Bougie	Device Label Bougie	Passed
IFU	IFU which shall contain all relevant information regarding [DI] and [ER].	Passed
ScalpelCric	ScalpelCric Set can be used in Operating condition	Passed
ScalpelCric	Functionality after simulated transport	Passed
Transport Validation	Functionality after simulated transport	Passed
Safety	Verify implementation and effectiveness of all Risk Control Measures defined in the Risk Analysis	Passed
Suction Cap	Connecting tube with open suction cap during ventilation	Passed
User Needs	User Needs for ScalpelCric, defined in [SoP]	Passed
ScalpelCric	Usability	Passed
Headerbag	Requirements of DIN EN ISO 11607-1 and DIN EN ISO 11607-2.	Passed
Sterilization	Sterilization Requirements for ScalpelCric	Passed
Business Needs	Business Needs for ScalpelCric	Passed
Label Sterile Packaging	Sterile packaging label which shall contain all relevant information regarding the [SFL], [DI] and [ER].	Passed
Label Outer Packaging	Outer packaging label which shall contain all relevant information regarding the [SFL], [DL] and [ER]	Passed
Packaging	Packaging Requirements for ScalpelCric	Passed
Accelerated Aging Syringe	Quality of the syringe after 5 years accelerated aging	Passed
Accelerated aging of Pouch	Function of the sterile packaging after 5 years accelerated aging	Passed
Bougie	Bougie shall fulfill all relevant specifications after 1 year accelerated aging	Passed
Scalpel	Function of the scalpel after accelerated aging 1 year	Passed
ScalpelCric	Scalpel Cric Set application oxygen resistance after 1 year accelerated aging	Passed
Surgicric	Function and dimension after 5 years accelerated aging of the Surgicric and the function of the sterile packaging. The tested tube and sterile packaging	Passed

	are identical to the devices in ScapelCric.	
Surgicric	Function and dimension after 3 years real time aging of the Surgicric including Tubus and the function of the sterile packaging. The tested tube and sterile packaging are identical to the devices in ScapelCric.	Passed
Syringe	Quality of the syringe after 3 years real time aging	Passed
Bougie	Bougie shall fulfill all relevant specifications after 5 years accelerated aging	Passed
Scalpel	Function of the scalpel after 5 years accelerated aging	Passed
ScalpelCric Set	Application oxygen resistance after 5 years accelerated aging	Passed
Cuff Tube Collapse included in the ScalpelCric after 5 years of accelerated aging.	Test required by DIN EN ISO 5361:2013-03, Annex C: Resistance of the VBM tracheal tube ventilation lumen collapse with cuff inflated inside a cylinder.	Passed

10 Substantial Equivalence Summary / Conclusion

Based on available 510(k) information herein provided, ScalpelCric, CricothyrotomySet is considered substantially equivalent to the predicate device “Melker Cuffed Emergency Cricothyrotomy Catheter Set – Surgical” in terms of intended use, technology and performance specifications.

The VBM component “Extension Tube with Swivel Connector” has been compared separately to the reference device “Airway Connector with Flex Tube”. The substantially equivalence has been demonstrated in terms of clinical and biological characteristics as well as technical features.

The subject device and the predicate device have the same intended use and the differences in technological features do not raise different questions of safety and effectiveness.