October 19, 2017

Cook Incorporated
Rebecca Odulio (Li-Chun Liu)
Regulatory Affairs Specialist
750 Daniels Way. P.O. Box 489
Bloomington, Indiana 47402

Re: K172527
Trade/Device Name: Amplatz Renal Dilator Set, Catheter for Use with Amplatz Renal Dilator Set, Amplatz Dilator, Amplatz Renal Introducer, Amplatz Radiopaque TFE Sheath, Clear Amplatz Sheath with Radiopaque Stripe
Regulation Number: None
Regulation Name: Unclassified
Regulatory Class: Class II
Product Code: LJE
Dated: August 18, 2017
Received: August 21, 2017

Dear Rebecca Odulio (Li-Chun Liu):

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 (DICE) 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 (DICE) 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,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*

K172527

Device Name
Amplatz Renal Dilator Set

Indications for Use *(Describe)*
Amplatz Renal Dilator Set is intended for nephrostomy tract dilation and the placement of a sheath.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K172527

Device Name

Catheter for Use with Amplatz Renal Dilator Set

Indications for Use *(Describe)*

Catheter for Use with Amplatz Renal Dilator Set is intended to be used over a pre-positioned wire guide for percutaneous dilation and access of nephrostomy tract.

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)

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510(k) Number *(if known)*

K172527

Device Name
Amplatz Dilator

Indications for Use *(Describe)*
Amplatz Dilator is intended for nephrostomy tract dilation to allow for the placement of a sheath.

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)

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510(k) Number *(if known)*
K172527

Device Name
Amplatz Renal Introducer

Indications for Use *(Describe)*
Amplatz Renal Introducer is intended to be used for nephrostomy tract dilation and the placement of a sheath.

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)

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Indications for Use

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510(k) Number *(if known)*
K172527

Device Name
Amplatz Radiopaque TFE Sheath

Indications for Use *(Describe)*
Amplatz Radiopaque TFE Sheath is intended to be used as a working channel to maintain a previously established nephrostomy tract.

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)

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Indications for Use

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

510(k) Number *(if known)*

K172527

Device Name
Clear Amplatz Sheath with Radiopaque Stripe

Indications for Use *(Describe)*
Clear Amplatz Sheath with Radiopaque Stripe is intended to be used as a working channel to maintain a previously established nephrostomy tract.

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)

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WWW.COOKMEDICAL.COM

Section 2.0 510(k) Summary

Amplatz Renal Dilator Set
Catheter for Use with Amplatz Renal Dilator Set
Amplatz Dilator
Amplatz Renal Introducer
Amplatz Radiopaque TFE Sheath
Clear Amplatz Sheath with Radiopaque Stripe
Date Prepared: October 19, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Rebecca Odulio (Li-chun Liu)
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x104673
Contact Fax Number:	(812) 332-0281

Device Information:

Device Trade Name	Common Name	Product Code	Regulation Number /Regulation Name/Regulation Class/ Classification Panel
Amplatz Renal Dilator Set	Catheter, Nephrostomy	LJE	None, Unclassified, Class II, Gastroenterology/Urology
Catheter for Use with Amplatz Renal Dilator Set			
Amplatz Dilator			
Amplatz Renal Introducer			
Amplatz Radiopaque TFE Sheath			
Clear Amplatz Sheath with Radiopaque Stripe			

Predicate Devices:

- K851144: 8/10 Dilator/Sheath Set; Amplatz Type Renal Dilator Sheath; Amplatz Type Renal Sheath; Clear Renal Sheath (Van-Tec, Inc.)
- K820865: Amplatz Type Graduated Renal Dilator; Fascial Dilators (Van-Tec, Inc.)

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Device Description:

The Amplatz Renal Dilator Set contains the following components: an 8.0 French Catheter for Use with Amplatz Renal Dilator Set, various fascial dilators, a 10.0 French introducer sheath, various Amplatz Dilators, and various Amplatz Renal Introducers (an assembly of Amplatz Dilator and Amplatz Sheath). The set is intended for nephrostomy tract dilation and the placement of a sheath, which acts as a working channel during percutaneous nephrostomy procedures. It is supplied sterile and intended for one-time use.

The set includes components that may be sold separately with dimensional and material variances compared to the specifications of the original set components. The set components that are available in single sellable unit are as follows:

- Amplatz Renal Dilator Set
- Catheter for Use with Amplatz Renal Dilator Set
- Amplatz Dilator
- Amplatz Renal Introducer
- Amplatz Radiopaque TFE Sheath;
- Clear Amplatz Sheath with Radiopaque Stripe

Indications for use:

The Amplatz Renal Dilator Set is intended for nephrostomy tract dilation and the placement of a sheath.

The Catheter for Use with Amplatz Renal Dilator Set is intended to be used over a pre-positioned wire guide for percutaneous dilation and access of nephrostomy tract.

The Amplatz Dilator is intended for nephrostomy tract dilation to allow for the placement of a sheath.

The Amplatz Renal Introducer is intended to be used for nephrostomy tract dilation and the placement of a sheath.

The Amplatz Radiopaque TFE Sheath is intended to be used as a working channel to maintain a previously established nephrostomy tract.

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The Clear Amplatz Sheath with Radiopaque Stripe is intended to be used as a working channel to maintain a previously established nephrostomy tract.

Comparison to Predicates:

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicates. The differences between the subject devices and the predicate devices include minor dimensional variations and materials. Characteristics of the subject devices that differ from the predicate devices are supported by testing. The subject devices do not raise new questions of safety or effectiveness as compared to the predicate devices.

Technological Characteristics:

The following tests have been conducted to demonstrate that the Amplatz Renal Dilator Set, Catheter for Use with Amplatz Renal Dilator Set, Amplatz Dilator, Amplatz Renal Introducer, and Amplatz Sheath (Amplatz Radiopaque TFE Sheath; Clear Amplatz Sheath with Radiopaque Stripe) met applicable design and performance requirements.

- Biocompatibility
- Compatibility Verification
- Functional Verification
- Radiopacity Verification
- Shelf Life of Three Years Accelerated Aging

Conclusion:

All predetermined acceptance criteria of the testing were met. Therefore, the results of these tests support a conclusion that the subject devices perform as intended and support a determination of substantial equivalence to the predicate devices.