

JAN 11 2000

178 K993455

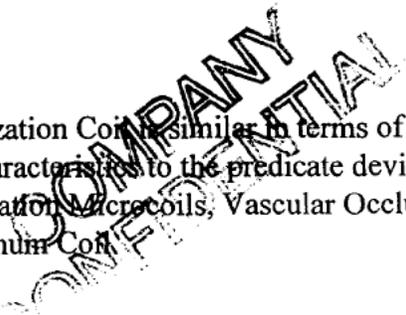
**Safety and Effectiveness Information**

**Submitted By:** Karen Bradburn  
Regulatory Affairs Coordinator  
COOK INCORPORATED  
925 South Curry Pike  
P.O. Box 489  
Bloomington, IN 47402  
(812) 339-2235

**Device:** Flipper™ Detachable Embolization Coil  
Device, Embolization, Arterial (79KRD)  
21 C.F.R. Part 870.3300

**Predicate Devices**

The Flipper™ Detachable Embolization Coil is similar in terms of intended use, materials of construction and technological characteristics to the predicate devices reviewed: Embolization Coil Positioner Set, Hilal Embolization Microcoils, Vascular Occlusion System, Guglielmi Detachable Coil and Fibered Platinum Coil.



**Device Description**

The Flipper™ Detachable Embolization Coil is used for arterial and venous embolization for the peripheral vasculature. This device is used in conjunction with the Flipper Detachable Coil Delivery Wire. The detachable coil delivery system provides safe delivery of embolization coils where the size of embolization coil is difficult to predetermine. A handle facilitates manipulation and provides safe and easy detachment of embolization coils. This device is provided sterile and is intended for one-time use.

The Flipper™ Detachable Embolization Coil consists of the embolization coils and the delivery wire. The embolization coils are manufactured using stainless steel wire with synthetic fibers. The delivery wire is manufactured using stainless steel with TFE coating. The device will be available in the following sizes and is compatible with catheters of 80 and 110 cm lengths.

Delivery Wire Diameter	0.035"
Extended Embolus Diameter	0.035"
Coil Length	3cm, 4cm, 5cm, 6cm, 8cm, 10cm, 12cm
Coil Embolus Diameter	3mm, 5mm, 6.5mm, 8mm

## Substantial Equivalence

The Flipper™ Detachable Embolization Coil is similar to many devices already in commercial distribution for arterial and venous embolization. These devices include an Embolization Coil Positioner Set (Cook Incorporated), Hilal Embolization Microcoils (Cook Incorporated), the Vascular Occlusion System (Cordis Endovascular Systems Inc.), the Guglielmi Detachable Coil (Target Therapeutics) and a Fibered Platinum Coil (Target Therapeutics). All devices are introduced via the percutaneous method of entry using a catheter or microcatheter introducer.

The Embolization Coil Positioner Set was reviewed as substantially equivalent under D.C. K940189 and is indicated for arterial and venous embolization. The device is constructed of stainless steel and synthetic fiber with a coil wire diameter of 0.018 to 0.038 inches. The coils are available in straight or curled shapes with an emboli size range of 2 to 20 mm. A push-button release mechanism is the method of deployment.

Hilal Embolization Microcoils were reviewed as substantially equivalent under D.C. K901337 and are indicated for the embolization of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.018 inches. The coils are available in straight and curled shapes with an emboli size range of 3 to 10 mm. Deployment is achieved by a wire guide which pushes the coil out of the catheter.

The Vascular Occlusion System was reviewed as substantially equivalent under D.C. K983483 and may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. It is intended for the interventional radiologic management of arteriovenous malformation, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord and spine. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.014 inches. The coils are available in straight, "C", flat spiral and complex shapes with an emboli size range of 2 to 10 mm. Deployment is achieved by a wire guide which pushes the coils out of the microcatheter.

The Guglielmi Detachable Coil was reviewed as substantially equivalent under D.C. K951256, K960705 and K962503 and is indicated for embolization of intracranial aneurysms, arteriovenous malformations, arteriovenous fistulae and arterial venous embolizations in the peripheral vasculature. The device is constructed of platinum with a coil wire diameter of 0.010 to 0.018 inches. The coils are available in a helical shape with an emboli size range of 2 to 20 mm. The coils are deployed by electrolytic detachment from the wire guide.

The Fibered Platinum coil was reviewed as substantially equivalent under D.C. K955293 and is indicated for arterial and venous embolization in the peripheral vasculature. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.010 to 0.035 inches. The coils are available in the following shapes: straight, C-shaped, helical and complex helical. The emboli size range is 2 to 30 mm. Deployment is achieved by a wire guide which pushes the coil out of the catheter.

**COOK INCORPORATED**

The Flipper™ Detachable Embolization Coil will be indicated for arterial and venous embolization for the peripheral vasculature. The delivery wire will be constructed of stainless steel with a diameter of 0.035 inches. The stainless steel coils with synthetic fiber will be available in curled shapes with an coil embolus diameter range of 3 to 8 mm. The coil is deployed when interlocking threads between the coils and the delivery wire are unscrewed.

**Performance Data**

The following tests have been performed to evaluate the ability of the Flipper Detachable Embolization Coil to perform in accordance with the requirements of the design plan.

- ❖ *In-Vitro* Performance Test: Loading, Passage and Deployment
- ❖ Tensile Test: Coil Thread/Delivery System
- ❖ Tensile Test: Torque Wire to Braid Solder Joint

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use for arterial and venous embolization in the peripheral vasculature.

COMPANY  
CONFIDENTIAL



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 11 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Karen Bradburn  
Regulatory Affairs Coordinator  
Cook, Inc.  
P.O. Box 489  
Bloomington, In 47402

Re: K993455  
Flipper™ Detachable Embolization Coil  
Regulatory Class: III  
Product Code: KRD  
Dated: October 12, 1999  
Received: October 13, 1999

Dear Ms. Bradburn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

Page 2 - Ms. Karen Bradburn

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Celia M. Witten". The signature is written in dark ink and is positioned above the typed name.

Celia M. Witten, Ph.D., M.D.

Acting Director

Division of Cardiovascular

Respiratory and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

510(k) Number (if known): K 993455

Device Name: Flipper™ Detachable Embolization Coil

Indications for Use: Used for arterial and venous embolization in the peripheral vasculature.

*Bill G. Lempert*  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K 993455

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_ Concurrence of CDRH, Office of Device Evaluation (ODE) \_\_\_\_\_

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-the-Counter Use \_\_\_\_\_

\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number \_\_\_\_\_

K993455/A1

**OmniSonics Medical Technologies, Inc**

Robert A Rabiner

November 19, 1999

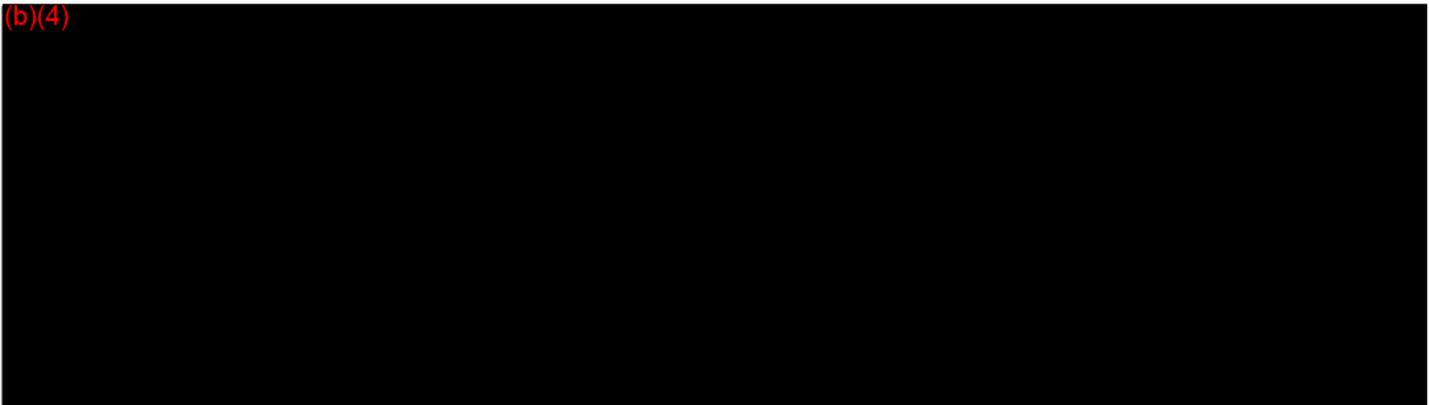
Food and Drug Administration  
Center for Devices and Radiological Health -  
Office of Device Evaluation  
510(k) Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, MD 20850

RE: K993455

Attn: Della Hammond

The following information is being submitted in response to your November 18, 1999 phone request for information on K993455. You requested the following information.

(b)(4)



If you need further information, please feel free to contact me at (508) 435-9893.

Sincerely,

Debbie Lampietro  
Consultant for OmniSonics

14 Equestrian Drive  
North Reading, MA 01864  
978 664 8440 978 664 4248  
info@Omnisonics.com

29 NOV 99 08 41  
FDA/CDRH/OCE/DHC

BR 3



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 11 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Karen Bradburn  
Regulatory Affairs Coordinator  
Cook, Inc.  
P.O. Box 489  
Bloomington, In 47402

Re: K993455  
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Regulatory Class: III  
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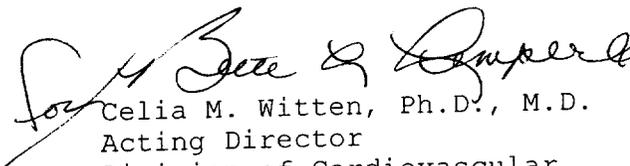
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Page 2 - Ms. Karen Bradburn

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Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Acting Director

Division of Cardiovascular

Respiratory and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

510(k) Number (if known): K 993455

Device Name: Flipper™ Detachable Embolization Coil

Indications for Use: Used for arterial and venous embolization in the peripheral vasculature.

*Bill D. Campbell*  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K 993455

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_ Concurrence of CDRH, Office of Device Evaluation (ODE) \_\_\_\_\_

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-the-Counter Use \_\_\_\_\_

\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number \_\_\_\_\_

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s)

JOHN KARAWIAN

Subject: 510(k) Number

K993455

To:

The Record - It is my recommendation that the subject 510(k) Notification:

Refused to accept.

Requires additional information (other than refuse to accept).

Is substantially equivalent to marketed devices.

NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES

NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?

YES

NO

Is this device subject to the Tracking Regulation?

YES

NO

Was clinical data necessary to support the review of this 510(k)?

YES

NO

Is this a prescription device?

YES

NO

Was this 510(k) reviewed by a Third Party?

YES

NO

Special 510(k)?

YES

NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers

YES

NO

This 510(k) contains:

Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)

A 510(k) summary OR  A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

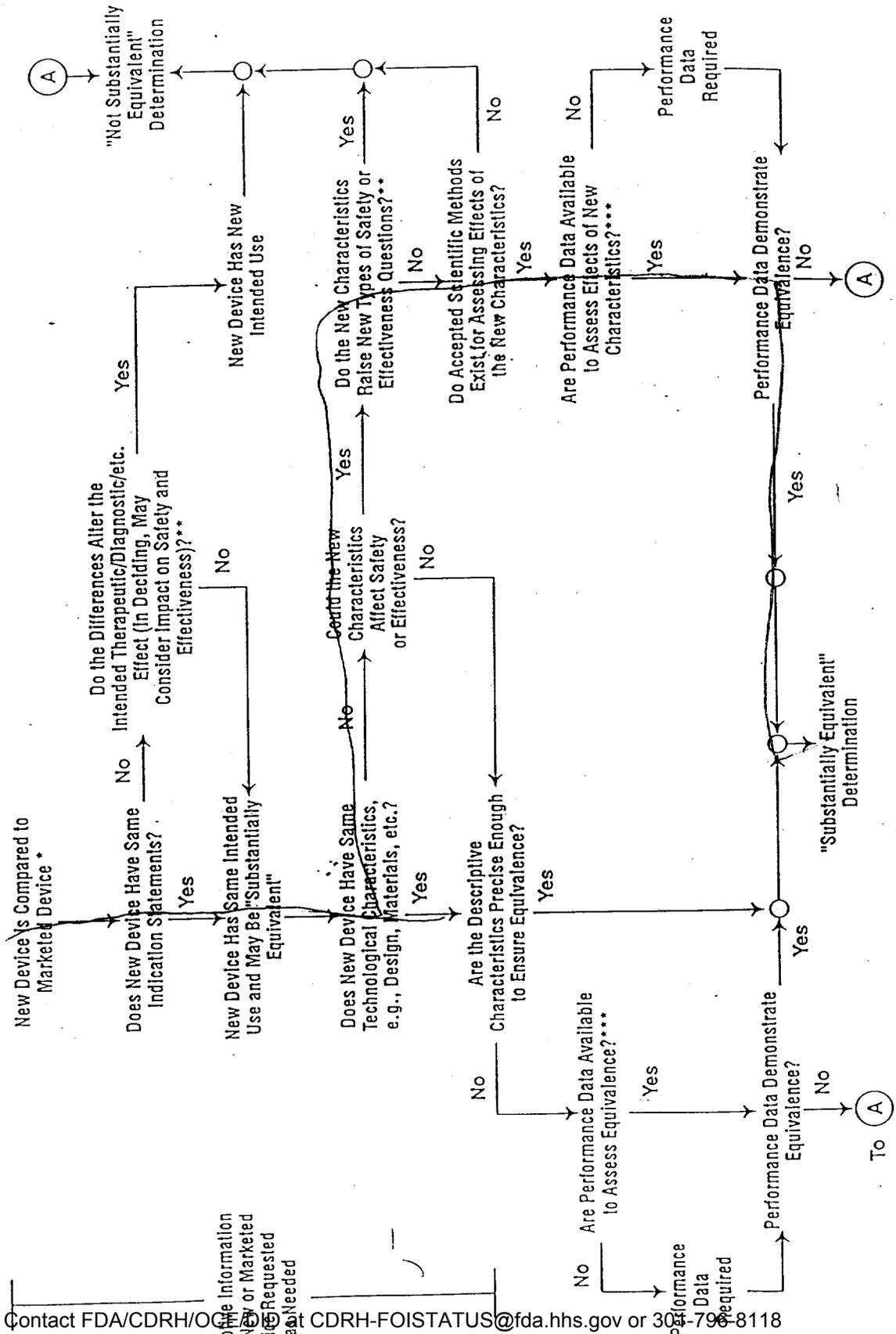
84 HCG CLASS III

Review: [Signature] (Branch Chief) CSFG (Branch Code) 10 Jan 00 (Date)

Final Review: [Signature] (Division Director) for CMW (Date) 10 Jan 00

4

# 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH/OCE/DTP at 1-800-FDA-1088 or CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

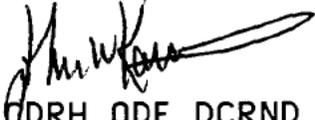
\* 510(k) Submissions/Additional Information (Pre-Amendments/Reclassified Post-Amendments) Devices is Unclear.  
 \*\* This Decision is Primarily Based on Descriptive Information Alone, But Additional Information is Sometimes Required.  
 \*\*\* Data May Be Available in 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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Memorandum

DATE: January 10, 2000 

FROM: JOHN W. KARANIAN, CDRH, ODE, DCRND, CSPDG

TO: File: K993455  
Firm: Cook Inc.  
Device: Flipper Detachable Embolization Coil  
Class: 21CFR 882.5950 Occlusion Coil, Artificial Embolization Device, Class III, 84 HCG

SUBJECT: Substantially Equivalent

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**Device/Application Summary**

The Flipper is similar to other occlusion coils cleared for use in the peripheral vasculature. The purpose of the present submission is to obtain an SE determination for the Flipper Detachable Embolization Coil indicated for arterial and venous embolization of the peripheral vasculature. The indications for use, materials and design of the Flipper are similar to that of the predicates (see comparison table pg 14) and are in support of an SE determination.

The Flipper device will be purchased as an assembly from (b)(4) and submitted to COOK Inc. to ensure quality control and perform sterilization of the device. The Flipper detachable coils are used with the Flipper delivery wire. (b)(4)

(b)(4) The device is provided sterile as a single-use device. These coils may be considered similar to Target's pushable Platinum Occlusion coils (K944293), and the Cook Company Occlusion Coils, cleared for use in both the peripheral and neurovasculature (K940189). The delivery method is percutaneous using a catheter introducer (K901337, K983483) and (b)(4) to deploy the coil(s). In K961923 the Berenstein coil was found to be substantially equivalent to currently marketed Target and Cook coils for use in both neuro and peripheral vasculature. With the provision of

-2-

adequate comparative (attachment 2), performance data (attachment 4), and appropriate predicates (K962503, K9444293, K901377), the data base supports the marketing and use of the Flipper device for peripheral indications.

## Submission Contents

### 1. Descriptive Information

(b)(4)

(b)(4). The coils are radiopaque for flouro visualization. The coils are available in a range of sizes compatible with commercially available 80 and 110cm length catheters.

All component materials, dimensions, features and functional specifications are described in tabular form with drawings (attachment 2 and 3). An adequate comparison to the predicates was provided (attachment 2, pg 14).

### 2. Performance

Adequate *in vitro* performance testing has been performed (b)(4)

(b)(4)

(b)(4)

(b)(4)

similar to that described in the Target Therapeutics K961923 for the Berenstein Coil for neuro vascular use. All test data was summarized. Complete data reports are provided in this original 510(k)(attachment 4, pg 44-47). The sponsor notes the selection of

-3-

appropriate (b)(4) (b)(4) is required for optimal results.

Functional bench testing was performed on the (b)(4) (b)(4) and adequately demonstrated the safety, effectiveness and performance integrity. (b)(4)

(b)(4) These tests demonstrate that the Coil can be delivered through the selected catheters without consequence. The probability of (b)(4) (b)(4) based on these data. In addition, the (b)(4) (b)(4)

No Animal testing was performed and is not considered necessary in view of the in vitro bench data.

### 3. Labeling and instructions for use

Labeling and instructions for use were provided (attachment 1) and adequately compared to the sited predicates (K901337, K983483, K962503, K941256) (attachment 2, pg 14-37). The labeling for the Flipper Coil is similar to that of the predicate Coil indication for use. The Instructions for Use are complete and clear regarding the intended use and instructions for operation.

### 4. Comparison Information

In general the information as provided suggest equivalence. The Flipper Coil is considered similar to sited predicates cleared for use in both the peripheral and neurovasculature (see comparison chart, attachment 2, pg 14). The delivery method for the Coil has been cleared for use and performed safely in fragile neuro vasculature and cerebral aneurysms during clinical use (K961923). With the provision of adequate performance data (attachment 4) the deployment method (screw mechanism) for the Flipper Coil should be considered safe and comparable to the predicate deployment methods.



-4-

Predicate device labeling was compared and demonstrated equivalence to that of the present submission. The physical characteristics of the Coil are comparable as described in the comparative table (attachment 2, pg 14). The anatomical sites for Flipper Coil therapy are certain vascular malformations (i.e., AVMs, AVFs) of the peripheral vasculature.

The design, materials and available sizes are within the range of predicates sited. Coil composition is identical to that of the predicate(s). Bench testing and biocompatibility testing were used to evaluate the performance of the subject coil as summarized in 2 above and 5 below, respectively. These data clearly establish that the subject Coil is similar to the predicate(s). When used as indicated the Flipper Coil should not raise safety or effectiveness issues which are different from the predicate(s).

## 5. Biocompatibility

Biocompatibility testing was performed on (b)(4) (b)(4) (b)(4) in accordance with the (b)(4) (b)(4) (b)(4). The data submitted for the (b)(4) (b)(4) biocompatible as summarized in attachment 5 (pg 58-174). The Coil materials (both synthetic fiber and stainless steel with TFE coating) passed (b)(4) (b)(4) (b)(4) testing. The materials were (b)(4) (b)(4) (b)(4) tests). Carcinogenicity testing was not performed due to the nontoxic properties of the Coil materials. All (b)(4) data were summarized in tabular and original form and provided.

## 6. Sterilization

The coils will be sterilized utilizing a valid (b)(4). Validation and assurance levels are similar to that of the predicate sterilization method. The validation method is based upon the (b)(4) (b)(4) method in the (b)(4) (b)(4). The SAL for all

-5-

coils was 1x10<sup>(b)</sup>. The sterilization methods for the subject Coil have not been changed and are the same as that described in the predicates sited.

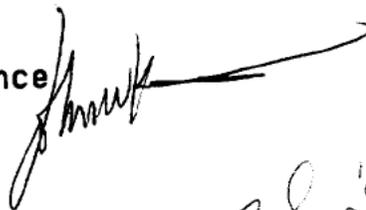
#### 7. SMDA information

The Sponsor submitted a summary of safety and effectiveness for the class III Cook Flipper Coil. In addition, a summary of safety and effectiveness problems associated with this type of device and the literature which the summary is based upon is provided (attachment 7).

#### 510(k) Decision Making Documentation

1. Is the product a device? Yes.
2. Is the device subject to 510(k)? Yes.
3. Is the new device compared to a legally marketed device? Yes.
4. Does the new device have the same indication statement? yes.
5. Does the new device have the same technological characteristics (e.g., design, materials, etc.)? no.
6. Do accepted scientific methods exist for assessing effects of the new characteristics. Yes.
7. Are performance data available to assess effects of new characteristics? Yes.
8. Performance data demonstrate equivalence? Yes.

Recommendation: Substantial Equivalence



30  
10 Jan '00

## Screening Checklist For all Premarket Notification 510(k) Submissions

<b>Device Name:</b>						K						
<b>Submitter (Company):</b>												
<b>Items which should be included (circle missing &amp; needed information)</b>						S P E C I A L	A B B R E V I A T E D		T R A D I T I O N A L		✓ IF ITEM IS NEEDED AND IS MISSING	
						YES	NO	YES	NO	YES	NO	
<b>1. Cover Letter clearly identifies Submission as:</b>												
a) "Special 510(k): Device Modification"						GO TO # 2,3		GO TO # 2,4,5		✓	GO TO #2 4,5	
b) "Abbreviated 510(k)"												
c) Traditional 510(k)												
<b>2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS</b>											✓ IF ITEM IS NEEDED	
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class										✓		
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA				NA		
d) compliance with Section 514 - performance standards						NA				NA		
e) address of manufacturer												
f) Truthful and Accurate Statement												
g) Indications for Use enclosure												
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)												
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)												
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals												
k) Proposed Labeling:												
i) package labeling (user info)												
ii) statement of intended use												
iii) advertisements or promotional materials												
i) MRI compatibility (if claimed)												
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:												
i) Labeling												
ii) intended use												
iii) physical characteristics												
iv) anatomical sites of use												
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification												
<b>3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE</b>												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												
b) STATEMENT - INTENDED USE AND INDICATIONS FOR												

<b>USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*</b>				
<b>c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*</b>			* If no - STOP not a special	
<b>d) Design Control Activities Summary</b>				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE</b>							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

inapplicable requirements or deviations noted below			
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)									
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:									
i) component & material									✓
ii) identify patient-contacting materials									✓
iii) biocompatibility of final sterilized product									✓
b) Sterilization and expiration dating information:									✓
i) sterilization method									✓
ii) SAL									✓
iii) packaging									✓
iv) specify pyrogen free									✓
v) ETO residues									✓
vi) radiation dose									✓
c) Software validation & verification:									N/A
i) hazard analysis									
ii) level of concern									
iii) development documentation									
iv) certification									

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening  Yes  No  
 Date: 10/15/99

Reviewer: Senora F. Smallwood  
 Concurrence by Review Branch: \_\_\_\_\_

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K \_\_\_\_\_

Reviewer: \_\_\_\_\_

Division/Branch: \_\_\_\_\_

Device Name: \_\_\_\_\_

Product To Which Compared (510(K) Number If Known): \_\_\_\_\_

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

14

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

**EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED**

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

**ATTACH ADDITIONAL SUPPORTING INFORMATION**

## ***Internal Administrative Form***

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

October 13, 1999

COOK, INC.  
925 S. CURRY PIKE  
P.O. BOX 489  
BLOOMINGTON, IN 47402  
ATTN: KAREN BRADBURN

510(k) Number: K993455  
Received: 13-OCT-1999  
Product: FLIPPER DETACHABLE  
EMBOLIZATION COIL

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Staff  
Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at [www.fda.gov](http://www.fda.gov) or 301-796-8118

K993455

A COOK GROUP COMPANY  
925 South Curry Pike P.O. Box 489  
Bloomington, IN 47402 U.S.A.  
Phone: 812-339-2235  
Telex: 6711161 COOK UW  
Telefax: 812-339-5369



October 12, 1999

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, MD 20850

RE: 510(k) Premarket Notification  
DEVICE: Flipper™ Detachable Embolization Coil

Dear Sir or Madam:

The purpose of this letter is to notify the Food and Drug Administration, Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, that COOK INCORPORATED intends to market and distribute an embolization coil.

COOK INCORPORATED's intent to market this device is confidential commercial information and we request that it be considered as such by the FDA and not be available through Freedom of Information except where required by law.

I certify, that in my capacity as Regulatory Affairs Coordinator, I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Sincerely,

COOK INCORPORATED

*Karen Bradburn*

Karen Bradburn  
Regulatory Affairs Coordinator

Enclosure

RECEIVED  
13 Oct 99 10 41  
FDA/CDRH/OCE/DIC

SK  
21

18

CV  
III

510(k) Number (if known): K 993455

Device Name: Flipper™ Detachable Embolization Coil

Indications for Use: Used for arterial and venous embolization in the peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_ Concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR Over-the-Counter Use \_\_\_\_\_

\_\_\_\_\_  
(Division Sign Off)  
Division of \_\_\_\_\_ Respiratory,  
and Neurology \_\_\_\_\_  
510(k) Number \_\_\_\_\_

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### 510(k) Required Elements Checklist

1. Identification
  - Applicant's Name and Address COOK INCORPORATED  
925 South Curry Pike  
P.O. Box 489  
Bloomington, IN 47402
  - Contact Person Karen Bradburn
  - Signature of Contact Person Karen Bradburn
  - Phone Number of Contact 800-346-2686 or 812-339-2235
  - Address of Manufacturing & Sterilization Site Same as above.
  - Date of Application October 12, 1999
2. Device Name
  - Proposed Classification Name Device, Embolization, Arterial  
79 KR D (21 C.F.R. 870.3300)
  - Trade/Proprietary Name Flipper™ Detachable Embolization Coil
3. Establishment Registration # 1820334
4. Classification Information
  - Class Class III
  - Panel Cardiovascular Panel
5. Standards No known standards established.
6. Draft Proposed Labeling Attachment 1
7. Substantial Equivalence Information Attachment 2
8. Device Description Attachment 3
9. Performance Data Attachment 4
10. Biocompatibility Information Attachment 5
11. Packaging and Sterilization Attachment 6
12. 510(k) Safety and Effectiveness Information Attachment 7
13. Truthful and Accurate Statement Attachment 8
14. Class III Certification and Summary Attachment 9

**ATTACHMENT 1**  
**DRAFT PROPOSED LABELING**

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**OUTER PACKAGE LABEL**

INTENDED FOR ONE-TIME USE. STERILE IF PACKAGE IS UNOPENED OR UNDAMAGED.  
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

REORDER#  
**FDW-35-110**

**FLIPPER™ DETACHABLE EMBOLIZATION COIL DELIVERY SYSTEM**

**\*\*USE ONLY .035" FLIPPER™ DETACHABLE EMBOLIZATION COILS\*\***

INCLUDES:

(1) FLIPPER™ DETACHABLE EMBOLIZATION COIL DELIVERY SYSTEM  
2.6 FR. O.D., 110CM LONG  
REQUIRED MINIMUM CATHETER ENDOLE SIZE .041" DIA.

\*REFER TO PRODUCT INSERT PRIOR TO USE\*  
WARNING: NOT RECOMMENDED FOR USE WITH  
POLYURETHANE OR POLYVINYLCHLORIDE CATHETERS,  
COILS MAY BECOME LODGED IN LUMEN.  
PATENT PENDING

LOT NO. SAMPLE  
DO NOT USE AFTER 2002/09  
QUICK REORDER# SAMPLE412

LGS 297

FDW-35-110



+ H69800041213



SAMPLE

A Cook Group Company  
PO Box 489 Bloomington, IN 47402 USA



**COOK®**

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**OUTER PACKAGE LABEL**

A Cook Group Company  
PO Box 489 Bloomington, IN 47402 USA



NL 1195

**FLIPPER™ DETACHABLE  
EMBOLIZATION COIL**

FMWCE - 35 - 10 - 5



+ H6980003871E

INTENDED FOR ONE-TIME  
USE. STERILE IF PACKAGE  
IS UNOPENED OR  
UNDAMAGED. Federal  
(U.S.A.) law restricts this  
device to sale by or on the  
order of a physician. STORE  
THIS PRODUCT IN A DARK,  
DRY, COOL PLACE. AVOID  
EXTENDED EXPOSURE TO  
LIGHT.

**10CM X 5MM**

REORDER#

**FMWCE - 35 - 10 - 5**

- \* .035" DIAMETER EMBOLUS
- \* NUMBER OF LOOPS 6.4
- \* 5MM DIAMETER

\*FOR USE WITH FLIPPER™ DETACHABLE EMBOLIZATION  
COIL DELIVERY SYSTEM

(ORDER# FDW - 35 - 110) REFER TO PRODUCT INSERT PRIOR TO USE\*

1 COIL PER PACKAGE PATENT# 5,417,708

LOT NO. SAMPLE  
DO NOT USE AFTER 2004/09

**QUICK REORDER# SAMPLE387**



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**SUGGESTED INSTRUCTIONS FOR USE**

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## FLIPPER™ DETACHABLE EMBOLIZATION COIL

### INFORMATION FOR USE

Used for arterial and venous embolization. The detachable coil delivery system provides safe delivery of embolization coils where the size of embolization coil is difficult to predetermine and where correct positioning is especially critical.

### PACKAGING

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light.

### INDICATIONS FOR USE

The product is designed to be used for arterial and venous embolization in the peripheral vasculature.

The embolization coil is delivered into the vascular system using a selective angiographic catheter without sideports.

The product is intended for use by physicians trained and experienced in vascular embolization techniques.

### CONTRAINDICATIONS

None known.

### WARNINGS AND PRECAUTIONS

- Upon removal from package, inspect the product to ensure no damage has occurred. Do not remove the coil from the cartridge.
- It is important to follow the loading procedure carefully in order to avoid complications during attachment and detachment of the coil.
- To determine correct catheter position, perform an angiogram prior to embolization.
- The angiographic catheter should be flushed with saline prior to introducing the detachable coil.
- After the detachable coil delivery system with the coil has been introduced into the catheter it is important that the coil does not exit the catheter tip until the mandril has been pulled back. Otherwise the catheter may become dislocated in the vessel.
- If difficulties occur when detaching the embolization coil, or if resistance is felt when withdrawing the delivery wire, do not attempt to withdraw the delivery wire. Remove the guiding catheter and the delivery wire with the coil simultaneously - and replace the whole system.
- Not recommended for use with polyurethane or polyvinylchloride catheter. Coils may become lodged in lumen.

### PRODUCT DESCRIPTION

#### DISTAL PART (Fig. 1)

- a) Detachable Embolization Coil
- b) Coil Loading Cartridge
- c) Straightening Mandril
- d) Coil Delivery Wire

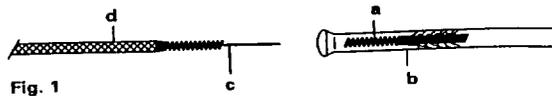


Fig. 1

#### PROXIMAL PART (Fig. 2)

- c) Straightening Mandril
- d) Coil Delivery Wire
- g) Pin Vise

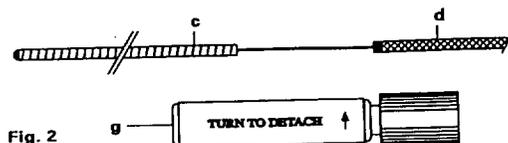


Fig. 2

### LOADING PROCEDURE

1. Introduce the straightening mandril (c) into the flared end of the cartridge (b) to engage the center of the coil (a) (Fig. 3).

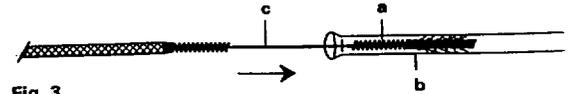


Fig. 3

2. Advance the "screw" portion of the coil delivery wire (d) until it reaches the embolization coil (a). It may be necessary to withdraw the straightening mandril a bit (Fig. 4).

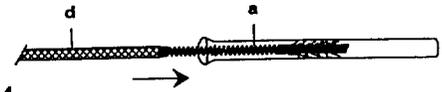


Fig. 4

3. Turn the cartridge (b) with embolization coil (a) clockwise to engage the screw threads between the embolization coil (a) and the delivery wire (d). (Fig. 5).
4. Continue the clockwise rotation of the detachable embolization coil (a) until the coil delivery wire (d) and the embolization coil (a) are almost completely joined (Fig. 5).

**Note:** In order to avoid difficulties in detaching the embolization coil (a) do not screw the coil (a) and the delivery wire completely together.

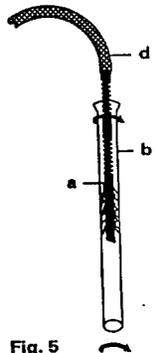


Fig. 5

5. If the embolization coil is not completely straightened, push the straightening mandril (c) from the proximal part into the delivery wire (d) to straighten the entire embolization coil (Fig. 6).
6. **Note:** Remove the embolization coil cartridge (b) over the proximal part.

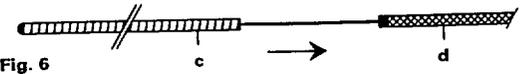


Fig. 6

7. Place the pin vise (g) over the proximal part of the delivery wire (d) and lock the pin vise (g) (Fig. 7).

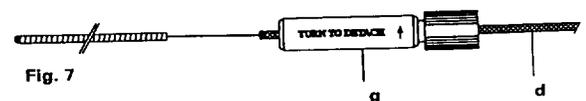


Fig. 7

(continued)

**SUGGESTED INSTRUCTIONS FOR USE**

1. Introduce the delivery wire (d) with the embolization coil (a) into a selectively placed catheter. Advance the delivery wire (d) and the embolization coil (a) under fluoroscopic control until the distal end of the embolization coil (a) is positioned at the distal end of the selective catheter but not beyond it. **Note: Do not rotate the delivery wire (d) during insertion through the catheter as inadvertent detachment of the embolization coil within the catheter might occur. Note: If the delivery wire tends to straighten and dislocate the angiography catheter, the straightening mandril (c) can be slightly withdrawn to soften the tip of the delivery wire.**
2. Withdraw the straightening mandril (c) by a distance equal to, or more than, the uncoiled length of the embolization coil (a) (Fig. 8).



Fig. 8

3. Advance the embolization coil (a) out of the tip of the selective catheter (f) into its desired position in the vessel (h) being embolized. **Warning: It is important that the screw-thread assembly between the coil and delivery wire remains fully within the distal end of the catheter. This prevents kinking of this portion of the device. Kinking will make detachment from the delivery wire difficult.** (Fig. 9)

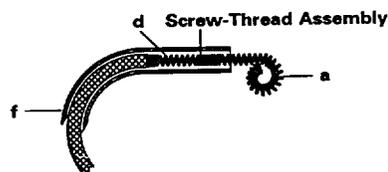


Fig. 9

4. If the embolization coil (a) position is unsatisfactory, pull the coil back into the catheter (f). Due to the risk of already beginning clot formation on the fibres, that will make detachment difficult, it is recommended to exchange the embolization coil before continuing the procedure. **Warning: If difficulties occur when detaching the embolization coil, or if resistance is felt when withdrawing the delivery wire, do not attempt to withdraw the delivery wire. Remove the guiding catheter and the delivery wire with the coil simultaneously - and replace the whole system.**
5. When the desired coil position is obtained, turn the delivery wire (d) counter-clockwise using the pin vise (g) until the coil is detached. Care should be taken during this manoeuvre to ensure that the screw-threads of the wire and coil remain within the distal end of the catheter. Gentle traction on the delivery wire (d) in between the turns will determine whether detachment has occurred. (Fig. 10).

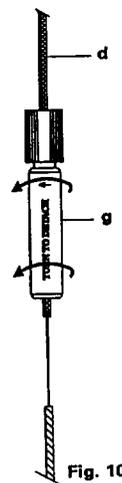


Fig. 10

6. Remove the delivery wire (d). If the proximal screw-thread of the coil has not exited the tip of the catheter, it should be pushed out using a floppy-tipped guide wire. Do not use the screw-thread of the delivery wire as entanglement may occur. Insert further embolization coils as required.

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**ATTACHMENT 2**  
**SUBSTANTIAL EQUIVALENCE INFORMATION**

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## Substantial Equivalence

The Flipper™ Detachable Embolization Coil is similar to many devices already in commercial distribution for arterial and venous embolization. These devices include an Embolization Coil Positioner Set (Cook Incorporated), Hilal Embolization Microcoils (Cook Incorporated), the Vascular Occlusion System (Cordis Endovascular Systems, Inc.), the Guglielmi Detachable Coil (Target Therapeutics) and a Fibered Platinum Coil (Target Therapeutics). All devices are introduced via the percutaneous method of entry using a catheter or microcatheter introducer.

The Embolization Coil Positioner Set was reviewed as substantially equivalent under D.C. K940189 and is indicated for arterial and venous embolization. The device is constructed of stainless steel and synthetic fiber with a coil wire diameter of 0.018 to 0.038 inches. The coils are available in straight or curled shapes with an emboli size range of 2 to 20 mm. A push-button release mechanism is the method of deployment.

Hilal Embolization Microcoils were reviewed as substantially equivalent under D.C. K901337 and are indicated for the embolization of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.018 inches. The coils are available in straight and curled shapes with an emboli size range of 3 to 10 mm. Deployment is achieved by a wire guide which pushes the coil out of the catheter.

The Vascular Occlusion System was reviewed as substantially equivalent under D.C. K983483 and may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. It is intended for the interventional radiologic management of arteriovenous malformation, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord and spine. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.014 inches. The coils are available in straight, "C", flat spiral and complex shapes with an emboli size range of 2 to 10 mm. Deployment is achieved by a wire guide which pushes the coils out of the microcatheter.

The Guglielmi Detachable Coil was reviewed as substantially equivalent under D.C. K951256, K960705 and K962503 and is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be: a) very high risk for management by traditional operative techniques, or, b) inoperable, and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature. The GDC is also intended for arterial and venous embolizations in the peripheral vasculature. The device is constructed of platinum with a coil wire diameter of 0.010 to 0.018 inches. The coils are available in a helical shape with an emboli size range of 2 to 20 mm. The coils are deployed by electrolytic detachment from the wire guide.

The Fibered Platinum coil was reviewed as substantially equivalent under D.C. K955293 and is indicated for arterial and venous embolization in the peripheral vasculature. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.010" to 0.035". The coils are available in the following shapes: straight, C-shaped, helical and complex helical. The emboli size range is 2 to 30 mm. Deployment is achieved by a wire guide which pushes the coil out of the catheter.

The Flipper™ Detachable Embolization Coil will be indicated for arterial and venous embolization for the peripheral vasculature. The delivery wire will be constructed of stainless steel with a diameter of 0.035". The stainless steel coils with synthetic fiber will be available in curled shapes with a coil embolus diameter range of 3 to 8 mm. The coil is deployed when interlocking threads between the coils and the delivery wire are unscrewed.

The similar indications for use and technological characteristics of the Flipper™ Detachable Embolization Coil as compared to the predicate devices support a determination of substantial equivalency.

A comparison of these devices is provided in the table which follows. Product information concerning the aforementioned devices also follows.

**COMPANY  
CONFIDENTIAL**

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COMPARISON TABLE

	Flipper™ Detachable Embolization Coil  Cook Incorporated	Embolization Coil Positioner Set  K940189  Cook Incorporated	Hilal Embolization Microcoils  K901337  Cook Incorporated	Vascular Occlusion System  K983483  Cordis Endovascular Systems, Inc.	Guglielmi Detachable Coil  K941256, K960705 and K962503  Target Therapeutics	Fibered Platinum Coil  K944293  Target Therapeutics
<b>Coil Material</b>	Stainless Steel with Synthetic Fiber	Stainless Steel with Synthetic Fiber	Platinum Coil with Synthetic Fiber	Platinum with Synthetic Fiber	Platinum	Platinum with Synthetic Fiber
<b>Coil Wire Diameter (in)</b>	0.035, 0.038	0.018 to 0.038	0.018	0.014	0.010 to 0.018	0.010 to 0.035
<b>Coil Shape</b>	Curled	Curled and Straight	Curled and Straight	Straight, C-shape, Helical and Complex	Helical	Straight, C-Shaped, Helical & Complex Helical
<b>Coil Diameter (mm)</b>	3 to 8	2 to 20	0	0	2 to 20	2 to 30
<b>Method of Deployment</b>	Screw mechanism	Push-button release mechanism	Wire guide pushes coil through catheter	Wire guide pushes coil through catheter	Wire & coil are electrolytically detached	Wire guide pushes coil through catheter
<b>Method of Introduction</b>	Percutaneous using a catheter introducer	Percutaneous using a catheter introducer	Percutaneous using a catheter introducer	Percutaneous using a microcatheter introducer	Percutaneous using a microcatheter introducer	Percutaneous using a catheter introducer
<b>Indications for Use</b>	Arterial and venous embolization for the peripheral vasculature	Arterial and venous embolization	Embolization of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine.	For the interventional radiologic management of arteriovenous malformation, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord and spine.	* See Substantial Equivalence	Arterial and venous embolizations in the peripheral vasculature
<b>Sterilization</b>	(b)(4)	(b)(4)	(b)(4)	Unknown	Unknown	Unknown
<b>Packaging</b>	(b)(4)	(b)(4)	(b)(4)	Unknown	Unknown	Unknown

COMPANY CONFIDENTIAL

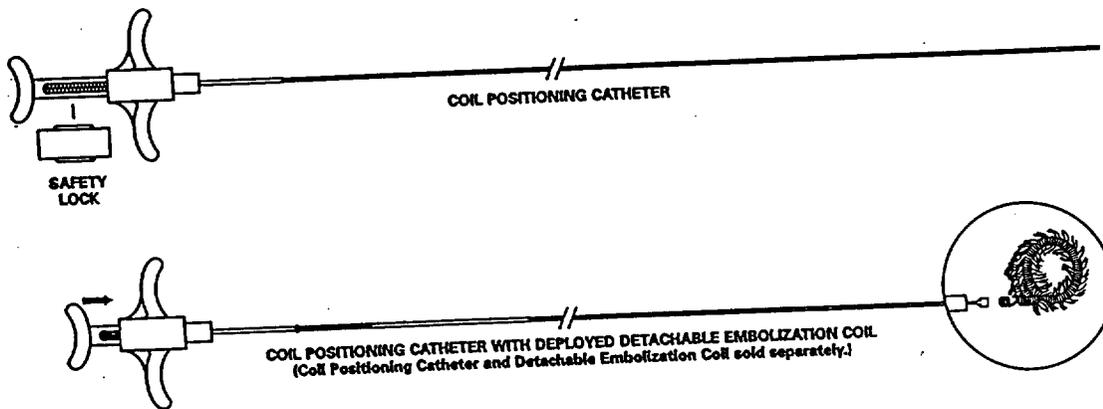
**EMBOLIZATION COIL POSITIONER SET**

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**EMBOLIZATION AND OCCLUSION**

**COIL POSITIONING CATHETERS**

Used to facilitate controlled release of Detachable Embolization Coils. The Coil Positioning Catheter allows precise positioning or repositioning of Detachable Embolization Coils within target vessels prior to deployment. The embolization coil is deployed with the use of a plastic release handle. The positioning catheter is designed for use with only Detachable Embolization Coils. Refer to Suggested Instructions for Use supplied with product for loading instructions and placement recommendations. Supplied sterile in peel-open packages. Intended for single-procedure use.



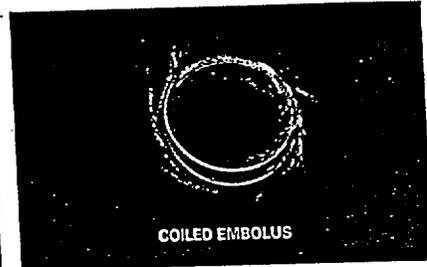
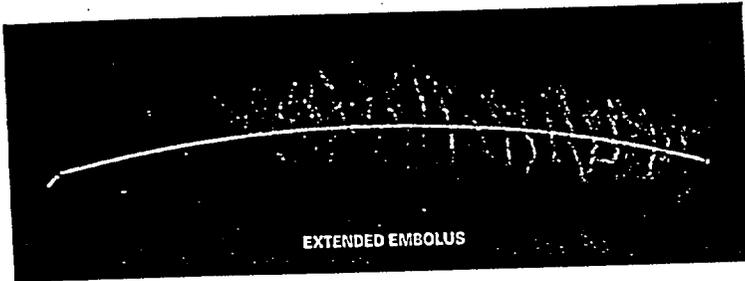
ORDER NUMBER	Outside Diameter	Length	Remarks	QUICK REORDER NUMBER <sup>1</sup>
ECPC-35-120	2.6 French	120 cm	For use with .035 inch (0.89 mm) diameter Detachable Embolization Coils	227899
ECPC-38-120	2.8 French	120 cm	For use with .038 inch (0.97 mm) diameter Detachable Embolization Coils	237741

<sup>1</sup>The Quick Reorder Number is for U.S.A. domestic use only.  
 Patent Numbers 5,354,623; 5,242,759; 5,417,708

**EMBOLIZATION AND OCCLUSION**

**DETACHABLE EMBOLIZATION COILS**

Used for embolization of selective vessel supply to arterio-venous malformations and other vascular lesions. Detachable Embolization Coils are designed for use with the Coil Positioning Catheter to permit accurate and precise delivery to the target vessel. Repositioning and withdrawal of the coil can be accomplished prior to coil release. The detachable coils are available in platinum or stainless steel coil with spaced synthetic fibers to promote maximum thrombogenicity. Refer to Suggested Instructions for Use supplied with Coil Positioning Catheter for loading instructions and placement recommendations. Supplied sterile in peel-open packages. Intended for one-time use.



ORDER NUMBER	EXTENDED EMBOLUS		COILED EMBOLUS		Remarks	QUICK REORDER NUMBER <sup>1</sup>
	Diameter	Length	Diameter	Configuration		
<b>STAINLESS STEEL</b> / <i>increased radial strength</i>						
MWCED-35-3-4	.035 inch (0.89 mm)	3 cm	4 mm	2 loops	Detachable embolization coils are used with an appropriately sized end hole catheter. Supplied one each per package.	231608
MWCED-35-3-5	.035 inch (0.89 mm)	3 cm	5 mm	2 loops		231791
MWCED-35-5-5	.035 inch (0.89 mm)	5 cm	5 mm	3 loops		231792
MWCED-35-5-8	.035 inch (0.89 mm)	5 cm	8 mm	2 loops		231293
MWCED-38-3-4	.038 inch (0.97 mm)	3 cm	4 mm	2 loops		237895
MWCED-38-5-5	.038 inch (0.97 mm)	5 cm	5 mm	3 loops		237890
MWCED-38-8-5	.038 inch (0.97 mm)	8 cm	5 mm	4 loops		237897
MWCED-38-5-8	.038 inch (0.97 mm)	5 cm	8 mm	2 loops		237896
MWCED-38-8-8	.038 inch (0.97 mm)	8 cm	8 mm	3 loops		237891
MWCED-38-9-8	.038 inch (0.97 mm)	9 cm	8 mm	3 loops		237898
MWCED-38-10-8	.038 inch (0.97 mm)	10 cm	8 mm	4 loops	237899	

<sup>1</sup>The Quick Reorder Number is for U.S.A. domestic use only.

<sup>2</sup>Results of testing to assess MRI safety and compatibility using a 1.5 Tesla scanner indicate platinum coils present no additional risk or adverse effects in patients undergoing MRI.

Patent Number 5,417,708

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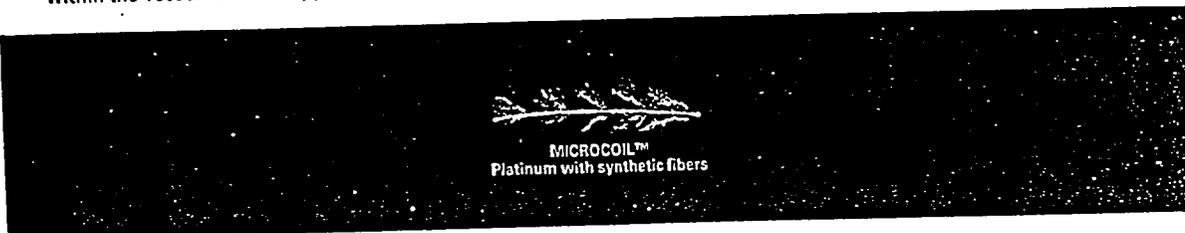
**HILAL EMBOLIZATION MICROCOILS™**

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**EMBOLIZATION AND OCCLUSION**

**HILAL EMBOLIZATION MICROCOILS™  
 STRAIGHT**

Used for embolization of selective vessel supply to arterio-venous malformations and other vascular lesions of the brain, spinal cord and spine. Design of the Microcoils™ permits introduction through small, pre-positioned delivery catheters. Coil design permits delivery into the target vessel by saline flush after initial advancement through the straightest segment of the catheter using the wire guide. The coils are made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum thrombogenicity. NOTE: Microcoils™ may be used in conjunction with particulate or liquid embolization materials. Final positioning of Microcoils™ creates a "platinum cast" effect within the vessel lumen. Supplied sterile in peel-open packages. Intended for one-time use.



ORDER NUMBER	Length <sup>1</sup>	Configuration	Remarks
MWCE-18-0.5-0-HILAL	.5 cm	Straight	
MWCE-18-0.7-0-HILAL	.7 cm	Straight	Supplied 2 each per package
MWCE-18-1.0-0-HILAL	1.0 cm	Straight	
MWCE-18-1.5-0-HILAL	1.5 cm	Straight	

<sup>1</sup>Other coil lengths available upon request.

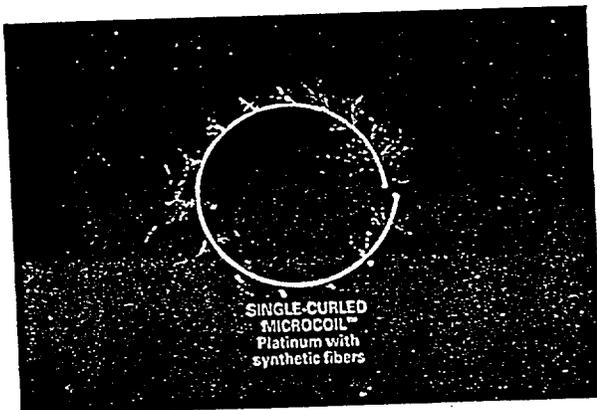
**DELIVERY CATHETER AND WIRE GUIDE RECOMMENDATIONS  
 FOR STRAIGHT AND CURLED MICROCOILS™**

- Microcoils™ are recommended for use through catheters designed for use with .018 inch (0.46 mm) diameter wire guides and whose inner diameter (ID) does not exceed .027 inch (0.69 mm) diameter. NOTE: COOK catheters appropriate for use are nontapered N3.0B nylon catheter and T3.0 and T3.0S TFE catheters.
- Microcoils™ are not recommended for use with polyurethane or polyvinylchloride catheters.
- Wire guides recommended for loading and positioning Microcoils™ are TFE coated .018 inch (0.46 mm) diameter with flexible tapered tips. NOTE: COOK Order Numbers: TSFNB-18-180, TSFNC-18-180.
- Refer to product insert for suggested instructions for use.

EMBOLIZATION AND OCCLUSION

**HILAL EMBOLIZATION MICROCOILS™**  
**SINGLE-CURLED AND MULTIPLE-CURLED COIL CONFIGURATIONS**

Used for embolization of selective vessel supply to arterio-venous malformations and other vascular lesions of the brain, spinal cord and spine. Design of the Microcoils™ permits introduction through small, pre-positioned delivery catheters. Coil design permits delivery into the target vessel by saline flush after initial advancement through the straightest segment of the catheter using the wire guide. The coils are made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum thrombogenicity. NOTE: Microcoils™ may be used in conjunction with particulate or liquid embolization materials. Final positioning of Microcoils™ creates a "platinum-cast" effect within the vessel lumen. Supplied sterile in peel-open packages. Intended for one-time use.



ORDER NUMBER	EXTENDED EMBOLUS		COILED EMBOLUS	Configuration	Remarks
	Diameter	Length	Diameter		
<b>SINGLE-CURLED COIL CONFIGURATIONS</b>					
MWCE-18-1.0-3-HILAL	.018 Inch (0.46 mm)	1.0 cm	3 mm	Single curl	Supplied 2 each per package
MWCE-18-1.5-5-HILAL	.018 Inch (0.46 mm)	1.5 cm	5 mm		
MWCE-18-2.1-7-HILAL	.018 Inch (0.46 mm)	2.1 cm	7 mm		
MWCE-18-3.0-10-HILAL	.018 Inch (0.46 mm)	3.0 cm	10 mm		
<b>MULTIPLE-CURLED COIL CONFIGURATIONS</b>					
MWCE-18-2.0-2-HILAL	.018 Inch (0.46 mm)	2.0 cm	2 mm	Multiple curls	Supplied 2 each per package
MWCE-18-2.0-4-HILAL	.018 Inch (0.46 mm)	2.0 cm	4 mm		
MWCE-18-3.0-3-HILAL	.018 Inch (0.46 mm)	3.0 cm	3 mm		
MWCE-18-3.0-4-HILAL	.018 Inch (0.46 mm)	3.0 cm	4 mm		
MWCE-18-4.0-6-HILAL	.018 Inch (0.46 mm)	4.0 cm	6 mm		
MWCE-18-4.0-7-HILAL	.018 Inch (0.46 mm)	4.0 cm	7 mm		
MWCE-18-6.0-5-HILAL	.018 Inch (0.46 mm)	6.0 cm	5 mm		
MWCE-18-6.0-7-HILAL	.018 Inch (0.46 mm)	6.0 cm	7 mm		
MWCE-18-6.0-10-HILAL	.018 Inch (0.46 mm)	6.0 cm	10 mm		

**VASCULAR OCCLUSION SYSTEM**

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## TRUFILL Pushable Coil Vascular Occlusion System

TRUFILL Pushable Coils, TRUPUSH Coil  
Pusher, TRANSIT and RAPIDTRANSIT  
Microcatheters

### Better Components Make a Better System

Cordis has now developed a pushable coil vascular occlusion system that delivers dependable and consistent performance. The Cordis TRUFILL pushable coil vascular occlusion system and its components are designed to surpass competing products by providing increased coil pusher durability with minimal coil deployment force even after multiple uses. TRUFILL pushable coils and the TRUPUSH coil pusher are compatible with .021" ID infusion catheters such as the TRANSIT and RAPIDTRANSIT microcatheters.

### TRUFILL Pushable Coils: Sophisticated Engineering and Quality Construction Is Evident in Every TRUFILL Pushable Coil

- Dense nylon fiber construction designed to increase thrombogenic potential and maximize occlusion characteristics.
- Integrated uniform nylon fiber distribution reduces frictional resistance for easy deployment, and less likelihood of device fatigue.
- Soft coil design allows for ease of coil deployment through the microcatheter and potentially more coils to be compacted into a lesion.
- Beaded atraumatic coil ends designed to reduce vessel trauma and catheter lumen damage.
- Transparent introducer with tapered tip.
  - Facilitates transition of coil into catheter.
  - Reduces possibility of catheter occlusion and lumen damage.
- Available in complex, flat spiral, straight and C shapes, in a wide range of sizes.

### TRUFILL Pushable Coils Specifications

- Wire material: Platinum
- Fiber: Nylon
- Coil OD: .014"
- Microcatheter compatibility: .021" ID
- Coil pusher compatibility: .016" min OD
- Recommended coil pusher: TRUPUSH coil pusher
- Recommended microcatheters: RAPIDTRANSIT and TRANSIT families

### TRUPUSH Coil Pusher: Durable, Dependable Performance

- State of the art kink resistant nitinol wire retains its shape and virtually eliminates coil pusher exchanges.
- Designed not to degrade even after multi-coil deployments.
- Exclusive dual marker bands enhance alignment in microcatheter and coil placement accuracy.
- Lubricious PTFE coating reduces coil pusher insertion friction and enhances durability.
- Blunted, soft .017" OD atraumatic tip designed to:
  - Maximize the surface contact with the embolic coil.
  - Minimize the possibility of microcatheter lumen damage from multiple coil deployments.

### TRUPUSH Coil Pusher Specifications

- Construction: Nitinol core-to-tip design, with dual tip markers – 3cm apart
- Overall length: 195 cm
- Taper length: 50cm
- Outer diameter: .016"/.017" prox./distal
- Coatings: Lubricious PTFE coated taper
- Microcatheter compatibility: .021" ID
- Recommended microcatheters: RAPIDTRANSIT and TRANSIT families

Interventional Neuroradiology

**TRUFILL**  
 Pushable Coil Vascular Occlusion System

TRUFILL Pushable Coils, TRUPUSH Coil Pusher, TRANSIT and RAPIDTRANSIT Microcatheters

TRUFILL Pushable Coils



Straight Shape



C Shape



Flat Spiral Shape

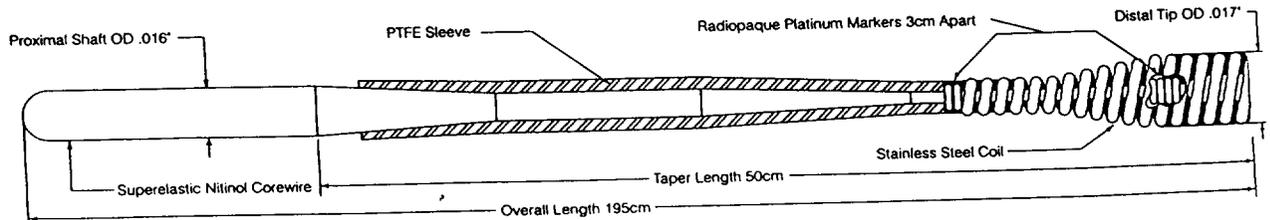


Complex Shape

Catalog Number	Shape	Length in Introducer, mm	Size, mm	Price (per box): Each catalog number must be ordered by the box.*
633-000	Straight	2	2	\$150.00
633-010	Straight	5	5	150.00
633-020	Straight	7	7	150.00
633-120	C	6	3	200.00
633-140	C	10	5	200.00
633-160	C	16	7	200.00
633-240	Flat Spiral	31	5	300.00
633-260	Flat Spiral	57	7	300.00
633-320	Complex	20	3	375.00
633-340	Complex	40	5	375.00
633-360	Complex	60	7	375.00
633-370	Complex	100	10	375.00

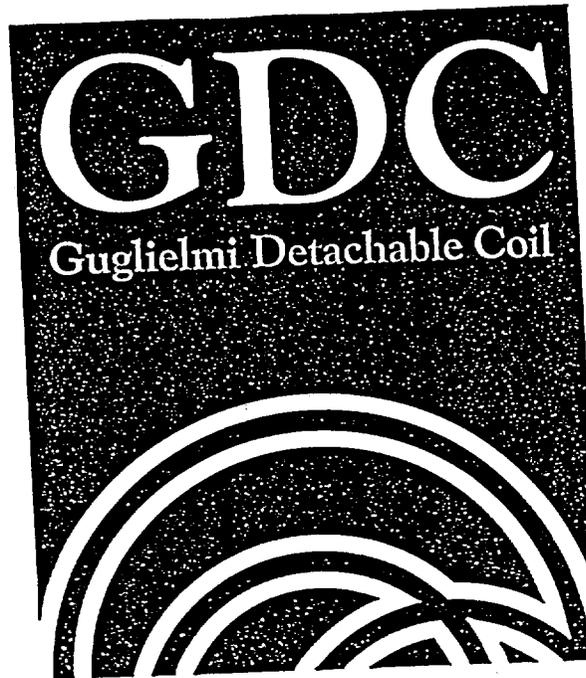
\*Packaged five coils per box. Each coil is supplied in a transparent nylon introducer with stylet.

TRUPUSH Coil Pusher



Catalog Number	Useable Length, cm	Taper, cm	Price (per unit): Each catalog number must be ordered in units of one (1).
632-774X	195	50	\$135.00

**GUGLIELMI DETACHABLE COIL®**



# Product Catalog & Price List

US Pricing Effective Fall 1995



W2

# GDC-10 Coils

Product No.	Description	Diameter x Length	Micro-Catheter Compatibility	Price per Unit (US\$)
341202	GDC-10 <i>soft</i>	2mm x 2cm	Tracker-10	\$425.00
341203	GDC-10 <i>soft</i>	2mm x 3cm	Tracker-10	\$425.00
341204	GDC-10 <i>soft</i>	2mm x 4cm	Tracker-10	\$425.00
341206	GDC-10 <i>soft</i>	2mm x 6cm	Tracker-10	\$425.00
341208	GDC-10 <i>soft</i>	2mm x 8cm	Tracker-10	\$425.00
341303	GDC-10 <i>soft</i>	3mm x 3cm	Tracker-10	\$425.00
341304	GDC-10 <i>soft</i>	3mm x 4cm	Tracker-10	\$425.00
341306	GDC-10 <i>soft</i>	3mm x 6cm	Tracker-10	\$425.00
341308	GDC-10 <i>soft</i>	3mm x 8cm	Tracker-10	\$425.00
341310	GDC-10 <i>soft</i>	3mm x 10cm	Tracker-10	\$425.00
340204	GDC-10	2mm x 4cm	Tracker-10	\$425.00
340208	GDC-10	2mm x 8cm	Tracker-10	\$425.00
340304	GDC-10	3mm x 4cm	Tracker-10	\$425.00
340306	GDC-10	3mm x 6cm	Tracker-10	\$425.00
340308	GDC-10	3mm x 8cm	Tracker-10	\$425.00
340312	GDC-10	3mm x 12cm	Tracker-10	\$425.00
340406	GDC-10	4mm x 6cm	Tracker-10	\$450.00
340410	GDC-10	4mm x 10cm	Tracker-10	\$450.00
340510	GDC-10	5mm x 10cm	Tracker-10	\$450.00
340515	GDC-10	5mm x 15cm	Tracker-10	\$450.00
340610	GDC-10	6mm x 10cm	Tracker-10	\$475.00
340620	GDC-10	6mm x 20cm	Tracker-10	\$475.00
340710	GDC-10	7mm x 10cm	Tracker-10	\$475.00
340730	GDC-10	7mm x 30cm	Tracker-10	\$475.00
340810	GDC-10	8mm x 10cm	Tracker-10	\$475.00
340820	GDC-10	8mm x 20cm	Tracker-10	\$475.00
340830	GDC-10	8mm x 30cm	Tracker-10	\$475.00
340915	GDC-10	9mm x 15cm	Tracker-10	\$475.00
340930	GDC-10	9mm x 30cm	Tracker-10	\$475.00
340103	GDC-10	10mm x 30cm	Tracker-10	\$500.00

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## GDC-18 Coils

Product No.	Description	Diameter x Length	Micro-Catheter Compatibility	Price per Unit (US\$)
351204	GDC-18 soft	2mm x 4cm	Tracker-18	\$425.00
351208	GDC-18 soft	2mm x 8cm	Tracker-18	\$425.00
351304	GDC-18 soft	3mm x 4cm	Tracker-18	\$425.00
351308	GDC-18 soft	3mm x 8cm	Tracker-18	\$425.00
351406	GDC-18 soft	4mm x 6cm	Tracker-18	\$450.00
351410	GDC-18 soft	4mm x 10cm	Tracker-18	\$450.00
350515	GDC-18	5mm x 15cm	Tracker-18	\$450.00
350520	GDC-18	5mm x 20cm	Tracker-18	\$450.00
350620	GDC-18	6mm x 20cm	Tracker-18	\$475.00
350730	GDC-18	7mm x 30cm	Tracker-18	\$475.00
350820	GDC-18	8mm x 20cm	Tracker-18	\$475.00
350830	GDC-18	8mm x 30cm	Tracker-18	\$475.00
350915	GDC-18	9mm x 15cm	Tracker-18	\$475.00
350930	GDC-18	9mm x 30cm	Tracker-18	\$475.00
350103	GDC-18	10mm x 30cm	Tracker-18	\$500.00
350123	GDC-18	12mm x 30cm	Tracker-18	\$500.00
350143	GDC-18	14mm x 30cm	Tracker-18	\$500.00
350163	GDC-18	16mm x 30cm	Tracker-18	\$535.00
350183	GDC-18	18mm x 30cm	Tracker-18	\$535.00
350203	GDC-18	20mm x 30cm	Tracker-18	\$535.00

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U.S. PRICE LIST  
AND ORDERING  
INFORMATION

For additional information  
contact your distributor or  
Boston Scientific Corporation

**Boston  
Scientific**  
**TARGET**

VJ

**detachable**  
**3D shape & 2-diameter**

**GDC® 3D SHAPE**

Product No.	Description	Big Loop OD	Length in Introducer	Recommended 2 Tip Catheter ID	Price per Coil \$
345304-3	GDC-10 3D Shape	3mm	4cm	.015"	825.00
345306-3	GDC-10 3D Shape	3mm	6cm	.015"	825.00
345406-3	GDC-10 3D Shape	4mm	6cm	.015"	850.00
345408-3	GDC-10 3D Shape	4mm	8cm	.015"	850.00
345610-3	GDC-10 3D Shape	6mm	10cm	.015"	875.00
345615-3	GDC-10 3D Shape	6mm	15cm	.015"	875.00
345820-3	GDC-10 3D Shape	8mm	20cm	.015"	900.00
345103-3	GDC-10 3D Shape	10mm	30cm	.015"	900.00
355615-3	GDC-18 3D Shape	6mm	15cm	.020"	875.00
355825-3	GDC-18 3D Shape	8mm	25cm	.020"	875.00
355103-3	GDC-18 3D Shape	10mm	30cm	.020"	900.00
355123-3	GDC-18 3D Shape	12mm	30cm	.020"	900.00
355143-3	GDC-18 3D Shape	14mm	30cm	.020"	935.00
355163-3	GDC-18 3D Shape	16mm	30cm	.020"	935.00
355183-3	GDC-18 3D Shape	18mm	30cm	.020"	935.00
355203-3	GDC-18 3D Shape	20mm	30cm	.020"	935.00

**GDC 2-DIAMETER** The GDC 2-Diameter's first 1.5 loops are 25% of the stated helical coil diameter.

Prod. No.	Description	Helical Coil Diameter	Length in Introducer	Recommended 2 Tip Catheter ID	Price per Coil \$
342308-3	GDC-10 2-Diameter	3mm	8cm	.015"	440.00
342410-3	GDC-10 2-Diameter	4mm	10cm	.015"	465.00
342515-3	GDC-10 2-Diameter	5mm	15cm	.015"	465.00
342620-3	GDC-10 2-Diameter	6mm	20cm	.015"	490.00
342725-3	GDC-10 2-Diameter	7mm	25cm	.015"	490.00
342830-3	GDC-10 2-Diameter	8mm	30cm	.015"	490.00
342930-3	GDC-10 2-Diameter	9mm	30cm	.015"	515.00
342103-3	GDC-10 2-Diameter	10mm	30cm	.015"	515.00
352520-3	GDC-18 2-Diameter	5mm	20cm	.020"	440.00
352620-3	GDC-18 2-Diameter	6mm	20cm	.020"	490.00
352730-3	GDC-18 2-Diameter	7mm	30cm	.020"	490.00
352830-3	GDC-18 2-Diameter	8mm	30cm	.020"	490.00
352930-3	GDC-18 2-Diameter	9mm	30cm	.020"	490.00
352103-3	GDC-18 2-Diameter	10mm	30cm	.020"	515.00
352123-3	GDC-18 2-Diameter	12mm	30cm	.020"	515.00
352143-3	GDC-18 2-Diameter	14mm	30cm	.020"	550.00
352163-3	GDC-18 2-Diameter	16mm	30cm	.020"	550.00
352183-3	GDC-18 2-Diameter	18mm	30cm	.020"	550.00
352203-3	GDC-18 2-Diameter	20mm	30cm	.020"	550.00

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**detachable**  
 standard GDC

**GDC® STANDARD**

Prod. No.	Description	Helical Coil Diameter	Length in Introducer	Recommended 2 Tip Catheter ID	Price per Coil \$
340204-3	GDC-10 Standard	2mm	4cm	.015"	425.00
340208-3	GDC-10 Standard	2mm	8cm	.015"	425.00
340304-3	GDC-10 Standard	3mm	4cm	.015"	425.00
340306-3	GDC-10 Standard	3mm	6cm	.015"	425.00
340308-3	GDC-10 Standard	3mm	8cm	.015"	425.00
340312-3	GDC-10 Standard	3mm	12cm	.015"	425.00
340406-3	GDC-10 Standard	4mm	6cm	.015"	450.00
340410-3	GDC-10 Standard	4mm	10cm	.015"	450.00
340510-3	GDC-10 Standard	5mm	10cm	.015"	450.00
340515-3	GDC-10 Standard	5mm	15cm	.015"	475.00
340610-3	GDC-10 Standard	6mm	10cm	.015"	475.00
340620-3	GDC-10 Standard	6mm	20cm	.015"	475.00
340710-3	GDC-10 Standard	7mm	10cm	.015"	475.00
340730-3	GDC-10 Standard	7mm	30cm	.015"	475.00
340810-3	GDC-10 Standard	8mm	10cm	.015"	475.00
340820-3	GDC-10 Standard	8mm	20cm	.015"	475.00
340830-3	GDC-10 Standard	8mm	30cm	.015"	500.00
350515-3	GDC-18 Standard	5mm	15cm	.020"	450.00
350520-3	GDC-18 Standard	5mm	20cm	.020"	450.00
350620-3	GDC-18 Standard	6mm	20cm	.020"	475.00
350730-3	GDC-18 Standard	7mm	30cm	.020"	475.00
350820-3	GDC-18 Standard	8mm	20cm	.020"	475.00
350830-3	GDC-18 Standard	8mm	30cm	.020"	475.00
350915-3	GDC-18 Standard	9mm	15cm	.020"	475.00
350930-3	GDC-18 Standard	9mm	30cm	.020"	475.00
350103-3	GDC-18 Standard	10mm	30cm	.020"	500.00
350123-3	GDC-18 Standard	12mm	30cm	.020"	500.00
350143-3	GDC-18 Standard	14mm	30cm	.020"	535.00
350163-3	GDC-18 Standard	16mm	30cm	.020"	535.00
350183-3	GDC-18 Standard	18mm	30cm	.020"	535.00
350203-3	GDC-18 Standard	20mm	30cm	.020"	535.00

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**detachable**  
**GDC soft & soft SR**

**GDC\* SOFT**

Prod. No.	Description	Helical Coil Diameter	Length in Introducer	Recommended 2 Tip Catheter ID	Price per Coil \$
341202-3	GDC-10 Soft	2mm	2cm	.015"	425.00
341203-3	GDC-10 Soft	2mm	3cm	.015"	425.00
341204-3	GDC-10 Soft	2mm	4cm	.015"	425.00
341206-3	GDC-10 Soft	2mm	6cm	.015"	425.00
341208-3	GDC-10 Soft	2mm	8cm	.015"	425.00
341303-3	GDC-10 Soft	3mm	3cm	.015"	425.00
341304-3	GDC-10 Soft	3mm	4cm	.015"	425.00
341306-3	GDC-10 Soft	3mm	6cm	.015"	425.00
341308-3	GDC-10 Soft	3mm	8cm	.015"	425.00
341310-3	GDC-10 Soft	3mm	10cm	.015"	450.00
341404-3	GDC-10 Soft	4mm	4cm	.015"	450.00
341406-3	GDC-10 Soft	4mm	6cm	.015"	450.00
341408-3	GDC-10 Soft	4mm	8cm	.015"	450.00
351204-3	GDC-18 Soft	2mm	4cm	.020"	425.00
351208-3	GDC-18 Soft	2mm	8cm	.020"	425.00
351304-3	GDC-18 Soft	3mm	4cm	.020"	425.00
351308-3	GDC-18 Soft	3mm	8cm	.020"	450.00
351406-3	GDC-18 Soft	4mm	6cm	.020"	450.00
351410-3	GDC-18 Soft	4mm	10cm	.020"	450.00
351508-3	GDC-18 Soft	5mm	8cm	.020"	450.00
351512-3	GDC-18 Soft	5mm	12cm	.020"	475.00
351610-3	GDC-18 Soft	6mm	10cm	.020"	475.00
351615-3	GDC-18 Soft	6mm	15cm	.020"	475.00

**GDC-10 SOFT SR (STRETCH RESISTANT)**

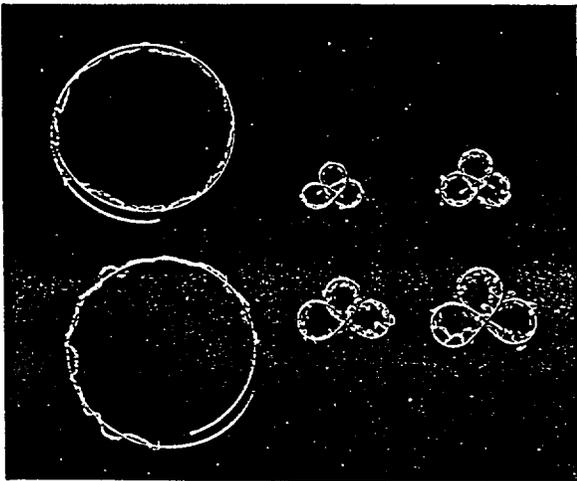
Prod. No.	Description	Helical Coil Diameter	Length in Introducer	Recommended 2 Tip Catheter ID	Price per Coil \$
341201-SR	GDC-10 Soft SR	2mm	1cm	.015"	625.00
341202-SR	GDC-10 Soft SR	2mm	2cm	.015"	625.00
341203-SR	GDC-10 Soft SR	2mm	3cm	.015"	625.00
341204-SR	GDC-10 Soft SR	2mm	4cm	.015"	625.00
341206-SR	GDC-10 Soft SR	2mm	6cm	.015"	625.00
341208-SR	GDC-10 Soft SR	2mm	8cm	.015"	625.00

10  
*WS*

**FIBERED PLATINUM COIL**

# FIBERED PLATINUM COILS

## VASCULAR OCCLUSION SYSTEM



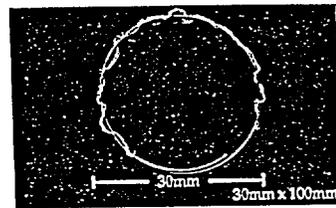
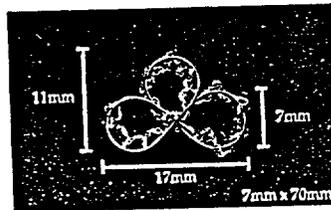
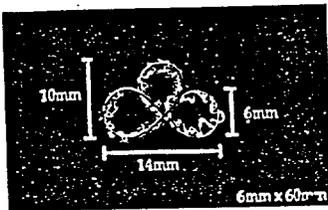
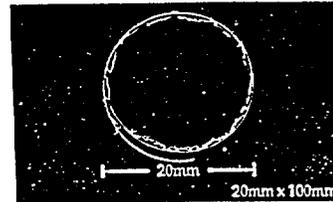
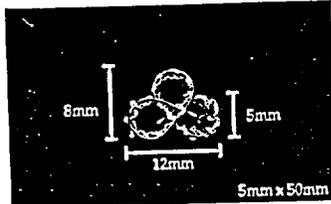
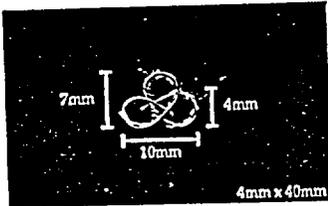
- Polyester Fiber promotes thrombosis.
- Platinum Fibered Coils are MRI compatible and non-ferromagnetic.
- Complex helical design permits complete spatial filling.
- Radiopaque for easy visualization.
- Polished, soft coil tips minimize vessel wall trauma.
- Secure interwoven fiber attachment.
- Coil Pusher for controlled delivery.
- Available in a variety of sizes and shapes.
- Designed for use with Tracker®-18 and Tracker®-18 Unibody™ Infusion Catheters.

### APPLICATIONS

- Arteriovenous malformations
- Arteriovenous fistulas
- Vein of Galen
- Tumor embolization
- Trauma
- The Vascular Occlusion System, allows superselective delivery of Polyester Fibered Coils to the smallest vasculature. The coils are indicated for preoperative vaso-occlusion and site specific flow reduction of vascular abnormalities in the central nervous system.



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Kit No./ Product No.	Coiled Diameter/ Length in Introducer	Unrestrained Diameter/ Length	Configuration
522044/312044	4 mm x 40 mm	7 mm x 10 mm	Complex Helical
522055/312055	5 mm x 50 mm	8 mm x 12 mm	Complex Helical
ring 92 522066/312066	6 mm x 60 mm	10 mm x 14 mm	Complex Helical
ring 92 522077/312077	7 mm x 70 mm	11 mm x 17 mm	Complex Helical
314210*	20 mm x 100 mm	20 mm	Helical
314310*	30 mm x 100 mm	30 mm	Helical

The Vascular Occlusion System(Kit) contains five coils and one Coil Pusher. Coils are each loaded in an introducer cannula and individually sterile pouched. Coils can also be ordered in a box of 5 without a Coil Pusher.  
 \* Not available in kit form.

1. Connect a continuous flush between the guiding catheter and Tracker®-18 Infusion Catheter.
2. Advance catheter to desired site.
3. Remove the coil retaining wire from the coil introducer. Wet the interior surface of the coil introducer prior to insertion.
4. Insert the coil introducer with the preloaded coil into the luer fitting. Using the plunger provided in the coil pouch, slowly advance the coil completely through the introducer and into catheter shaft.
5. Once the coil has entered the catheter shaft, remove the introducer and plunger from the catheter luer hub.
6. Use the stainless steel end (proximal end) of the Coil Pusher to advance coil approximately 1/4 (one quarter) of catheter's total length.
7. Thread the floppy end of the Coil Pusher into the catheter luer fitting. Continue to advance the coil through the catheter and carefully deposit coil. Hold the catheter in place while depositing the coil to prevent catheter tip movement. Once the coil has been deposited, discontinue advancing the coil pusher and remove the catheter.
8. Additional coils may be placed into the same or other sites by repeating the above procedure.

**TARGET**  
**THERAPEUTICS**  
 47201 Lakeview Blvd.  
 Fremont, CA 94538-6530  
 (925) 662-2415 (510) 440-7700  
 (800) 345-2498

F-075 3/92

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Key to symbols  
 HC = Hydrophobic Coating

**VORTX-35 COILS**

Prod. No.	Description	Apex Diameter	Base Diameter	Length of Coil in Introducer	Unrestrained Coil Length	Recommended Catheter	Price per Box of 5 Coils \$
373204	VortX-35 Coil	2.0mm	4.0mm	30mm	4.0mm	0.038" ID	275.00
373305	VortX-35 Coil	3.0mm	5.0mm	35mm	4.5mm	0.038" ID	275.00
373306	VortX-35 Coil	3.0mm	6.0mm	53mm	5.0mm	0.038" ID	275.00
373307	VortX-35 Coil	3.0mm	7.0mm	67mm	5.5mm	0.038" ID	275.00

**.035 FIBERED PLATINUM EMBOLIZATION COILS**

Prod. No.	Description	Secondary Coil Diameter	Length of Coil in Introducer	Unrestrained Coil Length	Recommended Catheter	Price per Box of 5 Coils \$
372301	.035 Fibered Coil	3mm	10mm	1.3mm	0.038" ID	225.00
372302	.035 Fibered Coil	3mm	20mm	2.6mm	0.038" ID	225.00
372304	.035 Fibered Coil	3mm	40mm	5.2mm	0.038" ID	225.00
372403	.035 Fibered Coil	4mm	30mm	2.9mm	0.038" ID	225.00
372503	.035 Fibered Coil	5mm	30mm	2.4mm	0.038" ID	225.00
372505	.035 Fibered Coil	5mm	50mm	4.0mm	0.038" ID	225.00
372604	.035 Fibered Coil	6mm	40mm	2.6mm	0.038" ID	225.00
372704	.035 Fibered Coil	7mm	40mm	2.3mm	0.038" ID	225.00
372906	.035 Fibered Coil	8mm	60mm	2.7mm	0.038" ID	225.00

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Key to symbols  
 HCP = Hydrophilic Coating



18 Systems

0.018" BRAIDED OCCLUSION DEVICE

Prod. No.	Description	Secondary Coil Diameter	Length In Introducer	Unrestrained Coil Length	Configuration	Recommended Micro-catheter	Price per Box of 10 Coils \$
332005	0.018" BOD Coils	Straight	5mm	5mm	Straight	FasTracker / TurboTracker 18	370.00
332007	0.018" BOD Coils	Straight	7mm	7mm	Straight	FasTracker / TurboTracker 18	370.00
332010	0.018" BOD Coils	Straight	10mm	10mm	Straight	FasTracker / TurboTracker 18	370.00
332308	0.018" BOD Coils	3mm	8mm	3mm	C-Shaped	FasTracker / TurboTracker 18	420.00
332514	0.018" BOD Coils	5mm	14mm	5mm	C-Shaped	FasTracker / TurboTracker 18	420.00
332720	0.018" BOD Coils	7mm	20mm	7mm	C-Shaped	FasTracker / TurboTracker 18	420.00
332128	0.018" BOD Coils	10mm	28mm	10mm	C-Shaped	FasTracker / TurboTracker 18	420.00

10 Systems

0.010" FIBERED PLATINUM

0.010" Fibered Platinum Coils are packaged 5 coils per box; Kit includes box of 5 coils with a Coil Pusher-10.

Prod. No.	Description	Secondary Coil Diameter	Length In Introducer	Unrestrained Coil Length	Configuration	Recommended Micro-catheter	Price per Box of 5 Coils / Kit Price \$
322002 / 540002	0.010" Fibered Coils	Straight	2mm	2mm	Straight	FasTracker / Tracker-10	170.00/275.00
322005 / 540005	0.010" Fibered Coils	Straight	5mm	5mm	Straight	FasTracker / Tracker-10	170.00/275.00
322037 / 540037	0.010" Fibered Coils	3mm	7mm	3mm	C-Shaped	FasTracker / Tracker-10	170.00/275.00

COIL PUSHERS

Prod. No.	Description	Total Length	Catheter Compatibility	Price per Unit \$
401210	Coil Pusher-10	177cm	FasTracker / Tracker-10	105.00

For best performance during coil delivery, we recommend an appropriately sized Coil Pusher

JS

**embolics**  
 pushable coils

Key to symbols  
 = Hydrophilic Coating

18 Systems

**VORTX DIAMOND SHAPE COILS**

Prod. No.	Description	Small Secondary Diameter	Large Secondary Diameter	Length of Coil in Introducer	Unrestrained Coil Length	Recommended Micro-catheter	Price per Box of 5 Coils \$
382203	Vortex Diamond Shape Coil	2mm	3mm	23mm	3.3mm	FasTracker / TurboTracker 18	395.00
382204	Vortex Diamond Shape Coil	2mm	4mm	41mm	3.7mm	FasTracker / TurboTracker 18	395.00
382205	Vortex Diamond Shape Coil	2mm	5mm	58mm	5.5mm	FasTracker / TurboTracker 18	395.00
382206	Vortex Diamond Shape Coil	2mm	6mm	80mm	6.7mm	FasTracker / TurboTracker 18	395.00

**VORTX-18 COILS**

Prod. No.	Description	Apex Diameter	Base Diameter	Length of Coil in Introducer	Unrestrained Coil Length	Recommended Micro-catheter	Price per Box of 5 Coils \$
381203	Vortex-18 Coil	2mm	3mm	22mm	2.5mm	FasTracker / TurboTracker 18	375.00
381204	Vortex-18 Coil	2mm	4mm	42mm	4.0mm	FasTracker / TurboTracker 18	375.00
381205	Vortex-18 Coil	2mm	5mm	60mm	5.5mm	FasTracker / TurboTracker 18	375.00
381206	Vortex-18 Coil	2mm	6mm	85mm	6.5mm	FasTracker / TurboTracker 18	375.00

**0.018" FIBERED PLATINUM COILS**

0.018" Fibered Platinum Coils are packaged 5 coils per box; Kit includes box of 5 coils with a Coil Pusher-16.

Prod. No./Kit No.	Description	Secondary Coil Diameter	Length in Introducer	Unrestrained Coil Length	Configuration	Recommended Micro-catheter	Box of 5 Coils/ Kit Price \$
312002 / No Kit	0.018" Fibered Coils	Straight	2mm	2mm	Straight	FasTracker / TurboTracker 18	160.00 / No. Kit
312005 / No Kit	0.018" Fibered Coils	Straight	5mm	5mm	Straight	FasTracker / TurboTracker 18	160.00 / No. Kit
312021 / 522021	0.018" Fibered Coils	2mm	10mm	5mm	Complex Helical	FasTracker / TurboTracker 18	290.00 / 395.00
312022 / 522022	0.018" Fibered Coils	2mm	20mm	4mm	Complex Helical	FasTracker / TurboTracker 18	290.00 / 395.00
312033 / 522033	0.018" Fibered Coils	3mm	30mm	6mm	Complex Helical	FasTracker / TurboTracker 18	290.00 / 395.00
312043 / 522043	0.018" Fibered Coils	4mm	30mm	7mm	Complex Helical	FasTracker / TurboTracker 18	290.00 / 395.00
312044 / 522044	0.018" Fibered Coils	4mm	40mm	10mm	Complex Helical	FasTracker / TurboTracker 18	315.00 / 410.00
312055 / 522055	0.018" Fibered Coils	5mm	50mm	12mm	Complex Helical	FasTracker / TurboTracker 18	315.00 / 410.00
312066 / 522066	0.018" Fibered Coils	6mm	60mm	14mm	Complex Helical	FasTracker / TurboTracker 18	315.00 / 410.00
312077 / 522077	0.018" Fibered Coils	7mm	70mm	17mm	Complex Helical	FasTracker / TurboTracker 18	315.00 / 410.00
314210 / No Kit	0.018" Vein of Galen	20mm	100mm	20mm	Helical	FasTracker / TurboTracker 18	320.00 / No. Kit
314310 / No Kit	0.018" Vein of Galen	30mm	100mm	30mm	Helical	FasTracker / TurboTracker 18	320.00 / No. Kit

**COIL PUSHERS**

Prod. No.	Description	Total Length	Catheter Compatibility	Price per Unit \$
401216	Coil Pusher-16	177cm	FasTracker / TurboTracker 18	95.00
401316	Coil Pusher-16	195cm	FasTracker / TurboTracker 18	100.00

For best performance during coil delivery, we recommend an appropriately sized Coil Pusher

M

**ATTACHMENT 3**  
**DEVICE DESCRIPTION**

**Device Description**

The Flipper™ Detachable Embolization Coil will be purchased as an assembly from (b)(4) (b)(4) which verifies that the company has a Quality System in place to control the manufacturing of this device. Incoming Quality Control procedures at COOK INCORPORATED will ensure that the devices meet the required specifications. Sterilization will be performed at COOK INCORPORATED.

The Flipper™ Detachable Embolization Coil is used for arterial and venous embolization for the peripheral vasculature. This device is used in conjunction with the Flipper Detachable Coil Delivery Wire. The detachable coil delivery system provides safe delivery of embolization coils where the size of embolization coil is difficult to predetermine. The embolization coil is deployed when the interlocking threads between the coil and the delivery wire are "unscrewed" by turning the delivery wire handle. This device is provided sterile and is intended for one-time use.

The embolization coils are contained in a coil loading cartridge. The embolization coils are manufactured using stainless steel wire with polymeric fibers. The delivery wire includes a wire coil, straightening mandril and a handle. The delivery wire is manufactured using stainless steel braiding soldered to a stainless steel coil wire with TFE coating. The straightening wire is manufactured using stainless steel. (b)(4)

The device will be available in the following sizes and is compatible with catheters of 80 and 110 cm lengths.

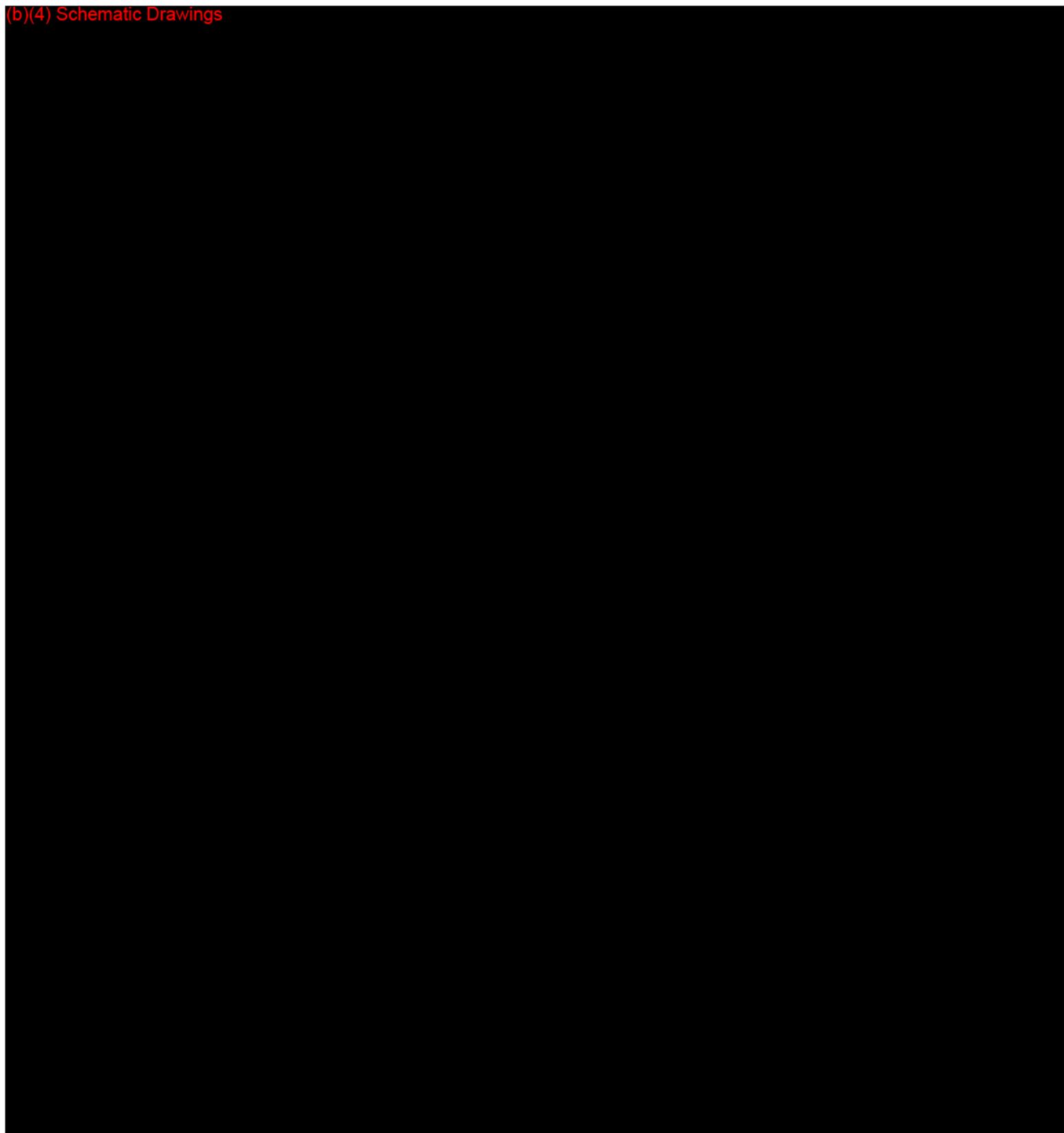
Delivery Wire Diameter	0.035"
Extended Embolus Diameter	0.035"
Coil Length	3cm, 4cm, 5cm, 6cm, 8cm, 10cm, 12cm
Coil Embolus Diameter	3mm, 5mm, 6.5mm, 8mm

A diagram is provided on the following page.

JK

**510(k) Premarket Notification**  
**Flipper™ Detachable Embolization Coil**  
**COOK INCORPORATED**

(b)(4) Schematic Drawings



**ATTACHMENT 4**  
**PERFORMANCE DATA**

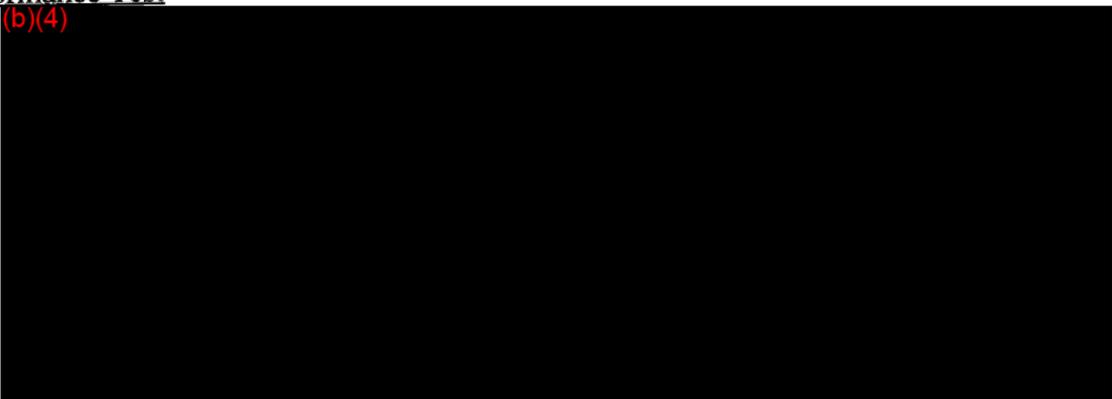
58

**Performance Data**

In-Vitro Performance Test

Purpose:

Conclusion:



Tensile Test: Coil Thread/Delivery System

Purpose:

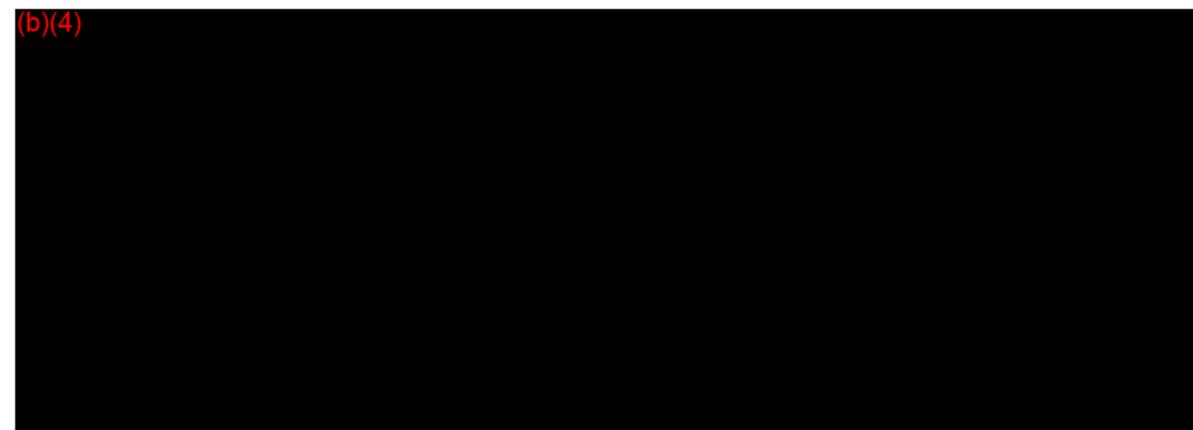
Conclusion:



Tensile Test: Torque Wire to Braid Solder Joint

Purpose:

Conclusion:



Copies of these test reports for the aforementioned performance tests are included on the following pages.

19

**STUDY TITLE:**

(b)(4)

**TEST ARTICLES:**

(b)(4)

**SUBMITTED TO:**

(b)(6)

VICE PRESIDENT  
REGULATORY AFFAIRS  
COOK INCORPORATED  
925 S. CURRY PIKE  
BLOOMINGTON, IN 47402

**SUBMISSION DATE:**

9-21-99

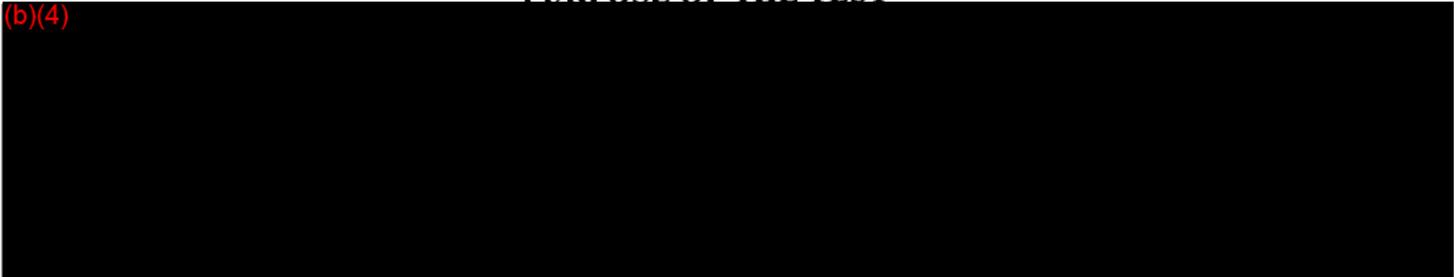
**TESTED BY:**

(b)(6)

PRODUCT DEVELOPMENT ENGINEER  
COOK INCORPORATED  
925 S. CURRY PIKE  
BLOOMINGTON, IN 47402

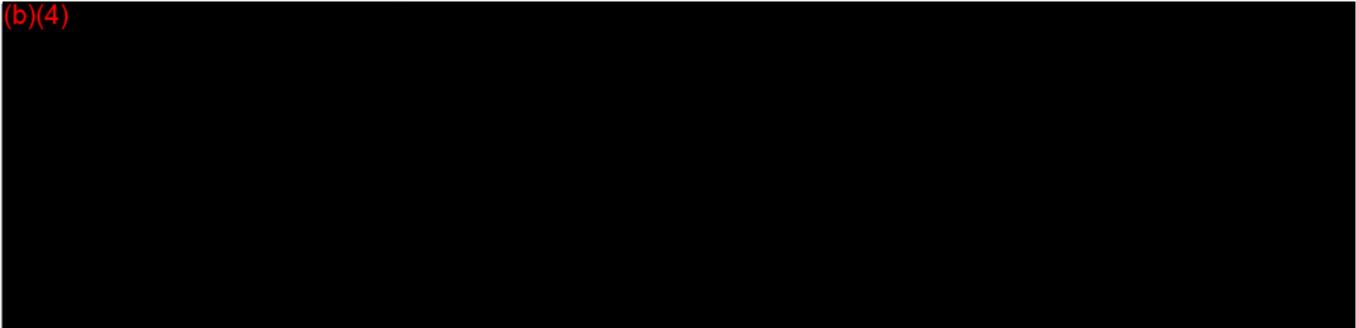
**PURPOSE OF THE TEST**

(b)(4)

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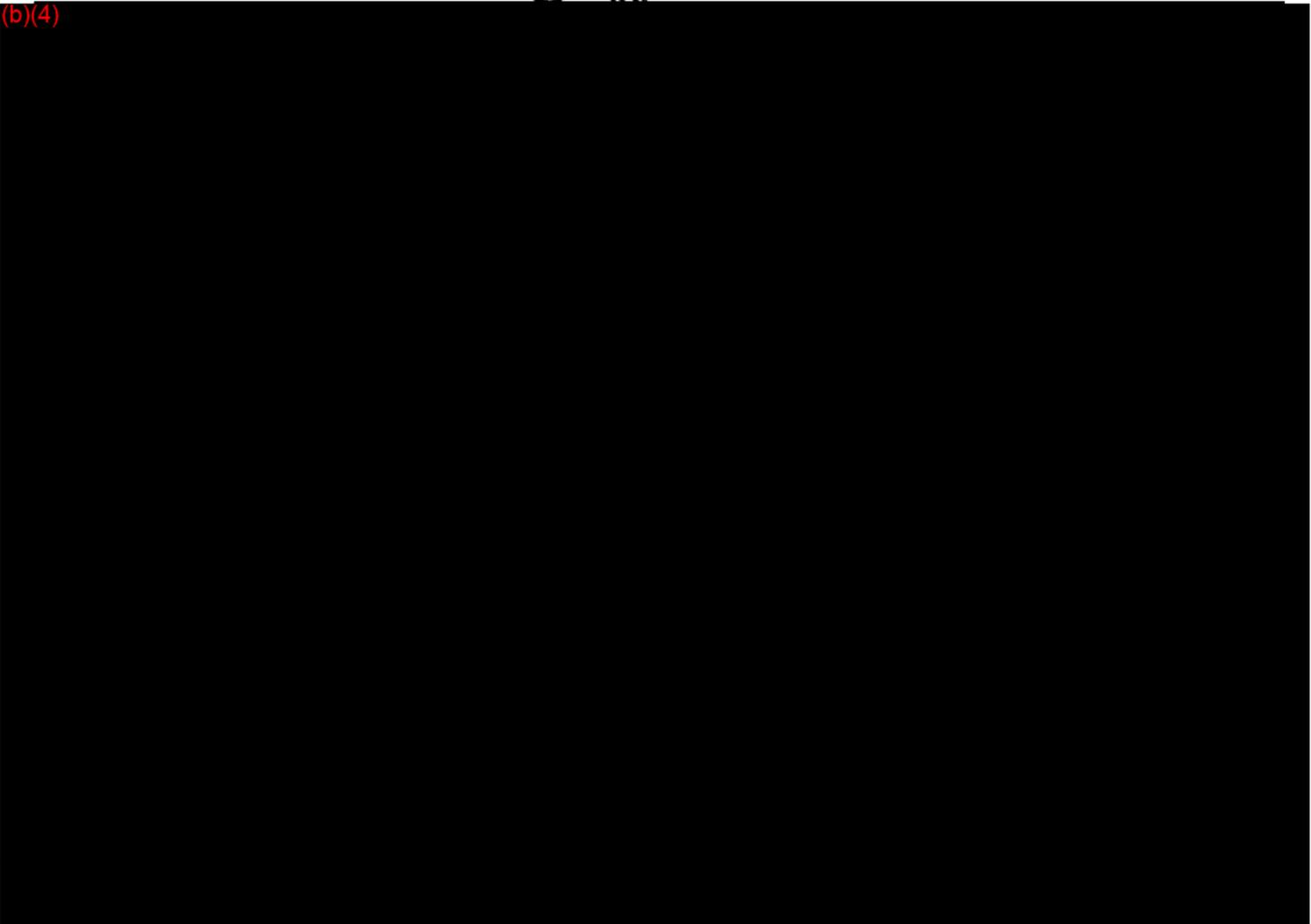
**GENERAL DESCRIPTION OF THE TEST**

(b)(4)

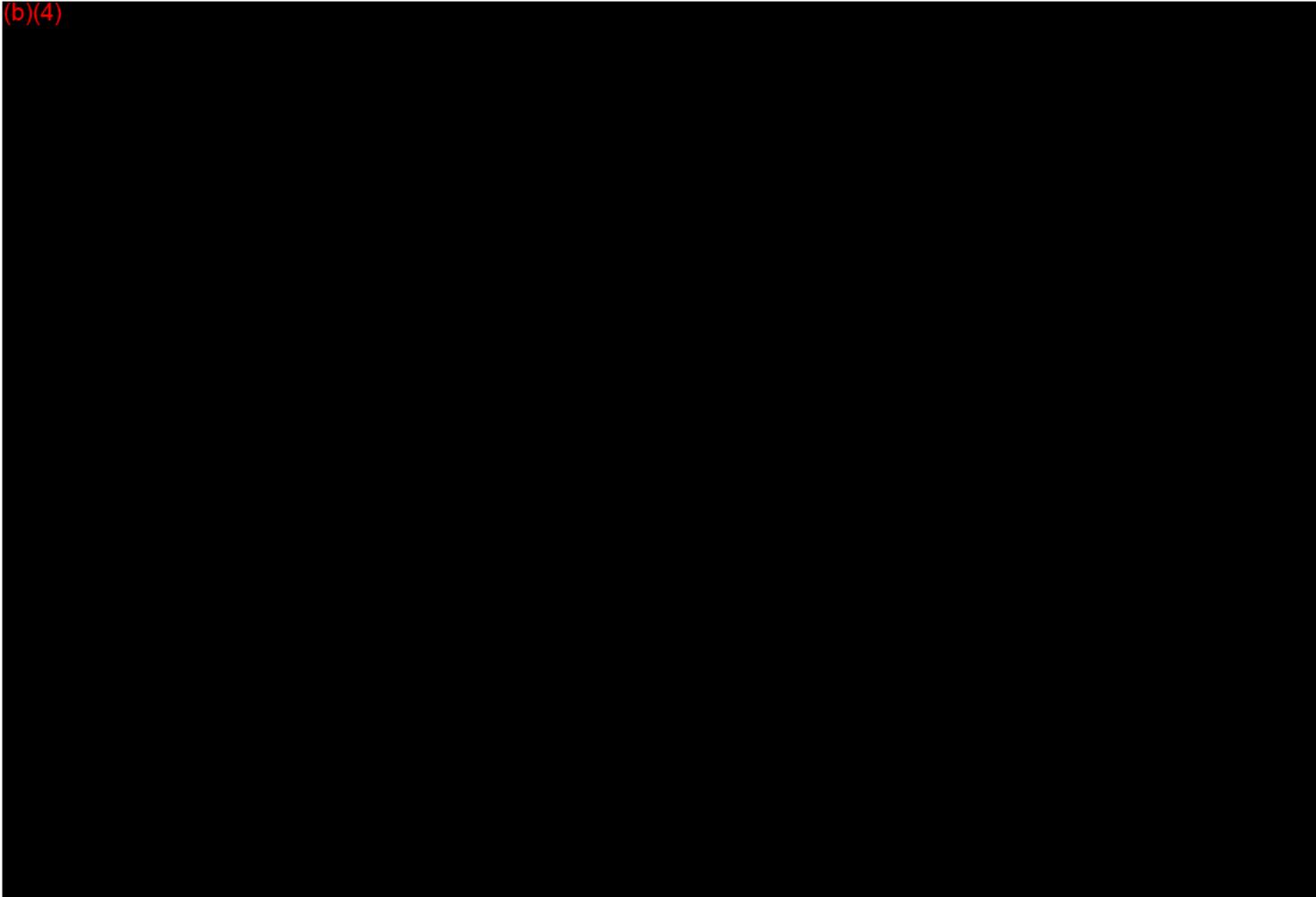
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**TEST METHOD**

(b)(4)

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(b)(4)



### **Experimental Results**

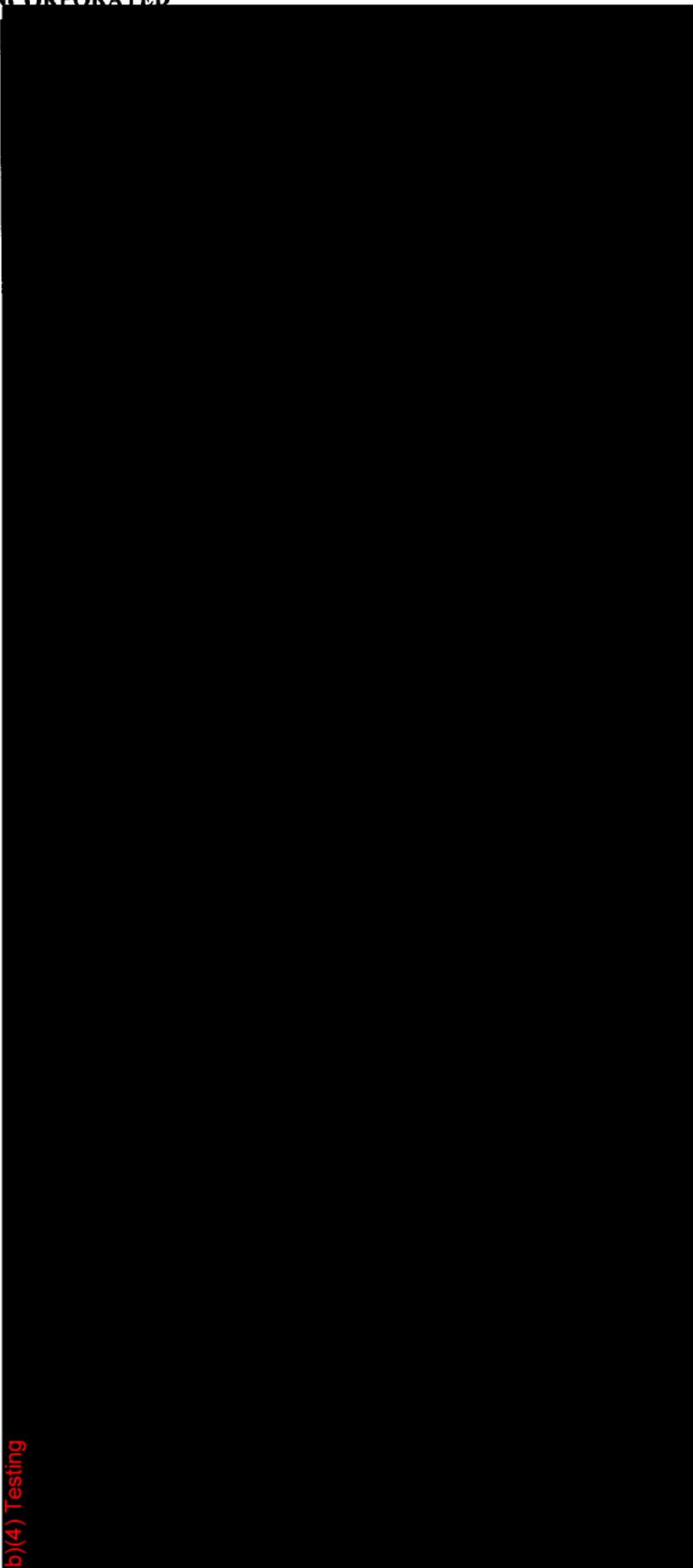
See sheet titled "Overall Evaluation Ratings" next page.

62

(b)(6)  
9-21-99

Jackson Detachable Coil Delivery System  
"FLIPPER"

### Overall Evaluation Ratings



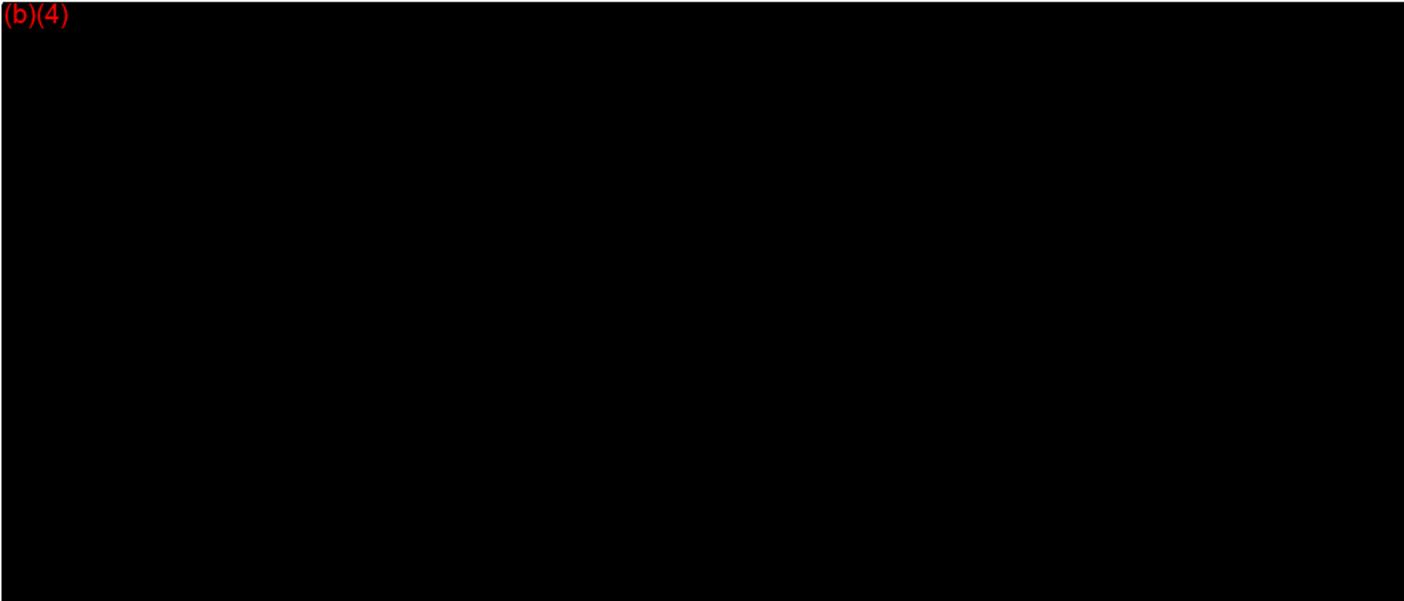
Project # (b)(4)

(b)(4) Testing

63

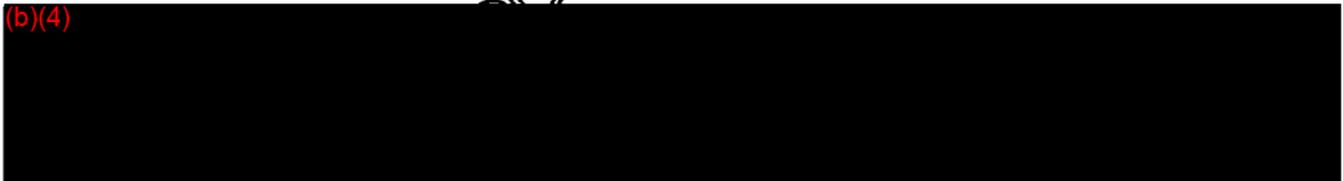
### Result Summary

(b)(4)



Conclusion

(b)(4)



64

**STUDY TITLE:**

JACKSON DETACHABLE COIL SYSTEM "FLIPPER"

(b)(4)

COIL THREAD / DELIVERY SYSTEM TENSILE TEST

PROJECT # (b)(4)

**TEST ARTICLES:**

(b)(4)

**SUBMITTED TO:**

(b)(6)

VICE PRESIDENT  
REGULATORY AFFAIRS  
COOK INCORPORATED  
925 S. CURRY PIKE  
BLOOMINGTON, IN 47402

**SUBMISSION DATE:**

9-27-99

**TESTED BY:**

(b)(6)

TESTING AND RELIABILITY ENGINEER  
&

(b)(6)

PRODUCT DEVELOPMENT ENGINEER  
COOK INCORPORATED  
925 S. CURRY PIKE  
BLOOMINGTON, IN 47402

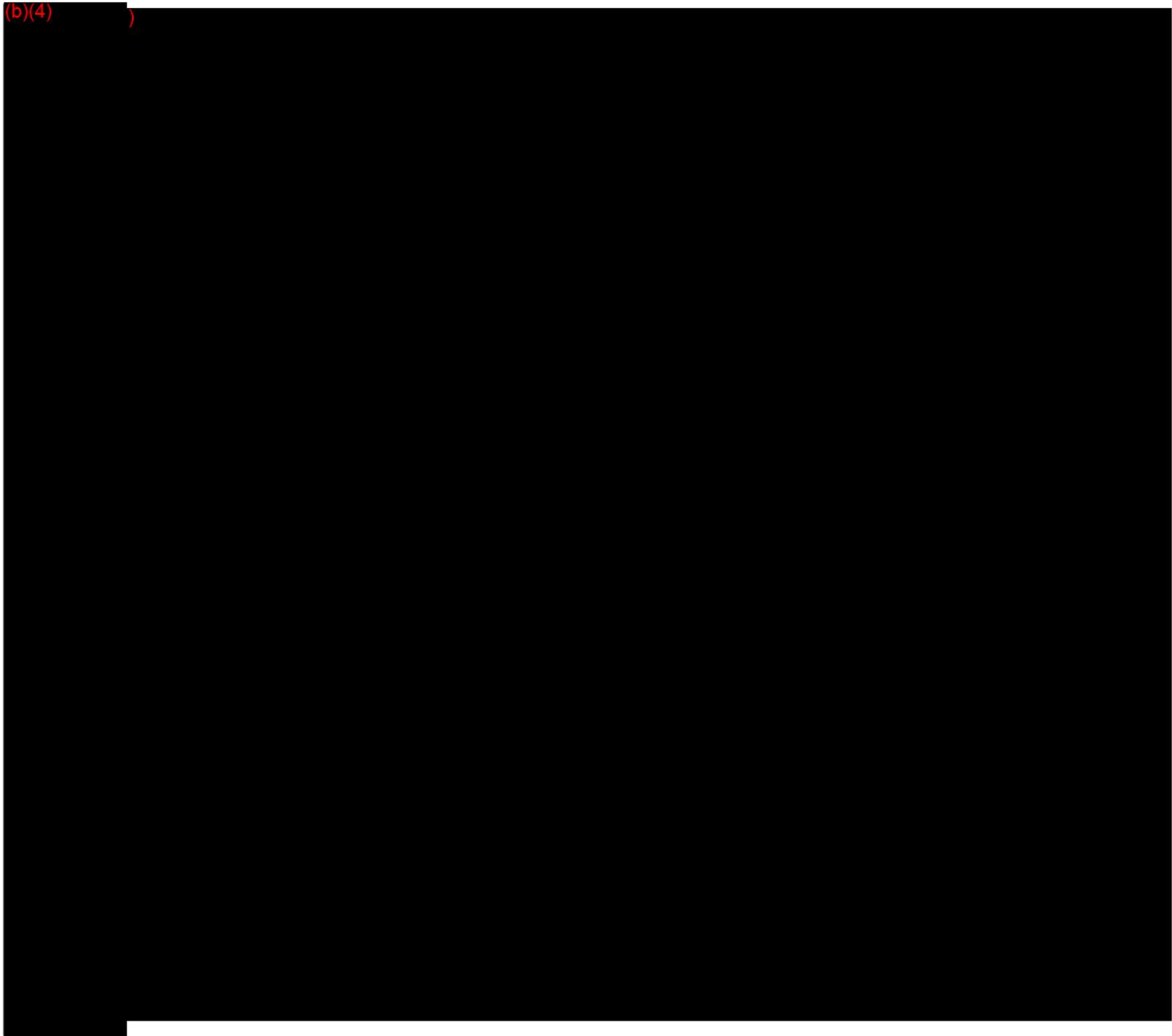
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(b)(4)

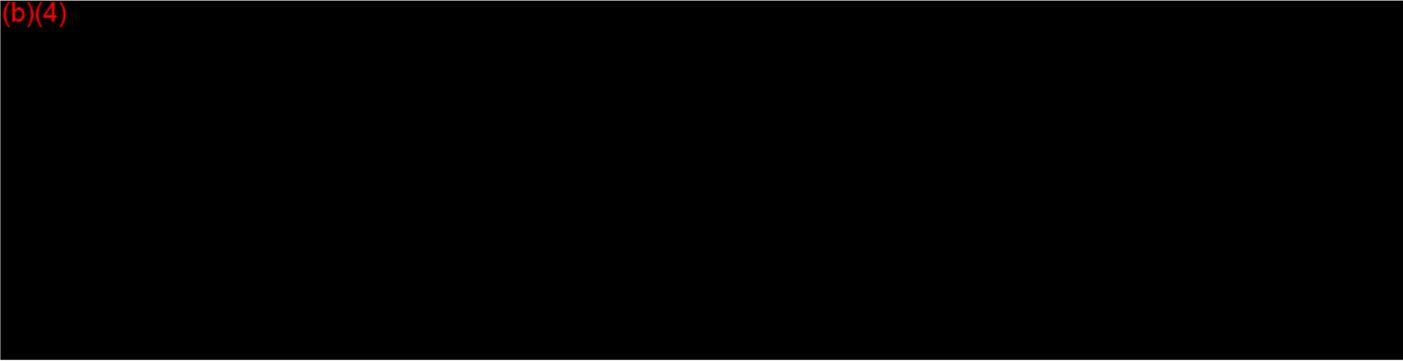
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**GENERAL DESCRIPTION OF THE TEST**

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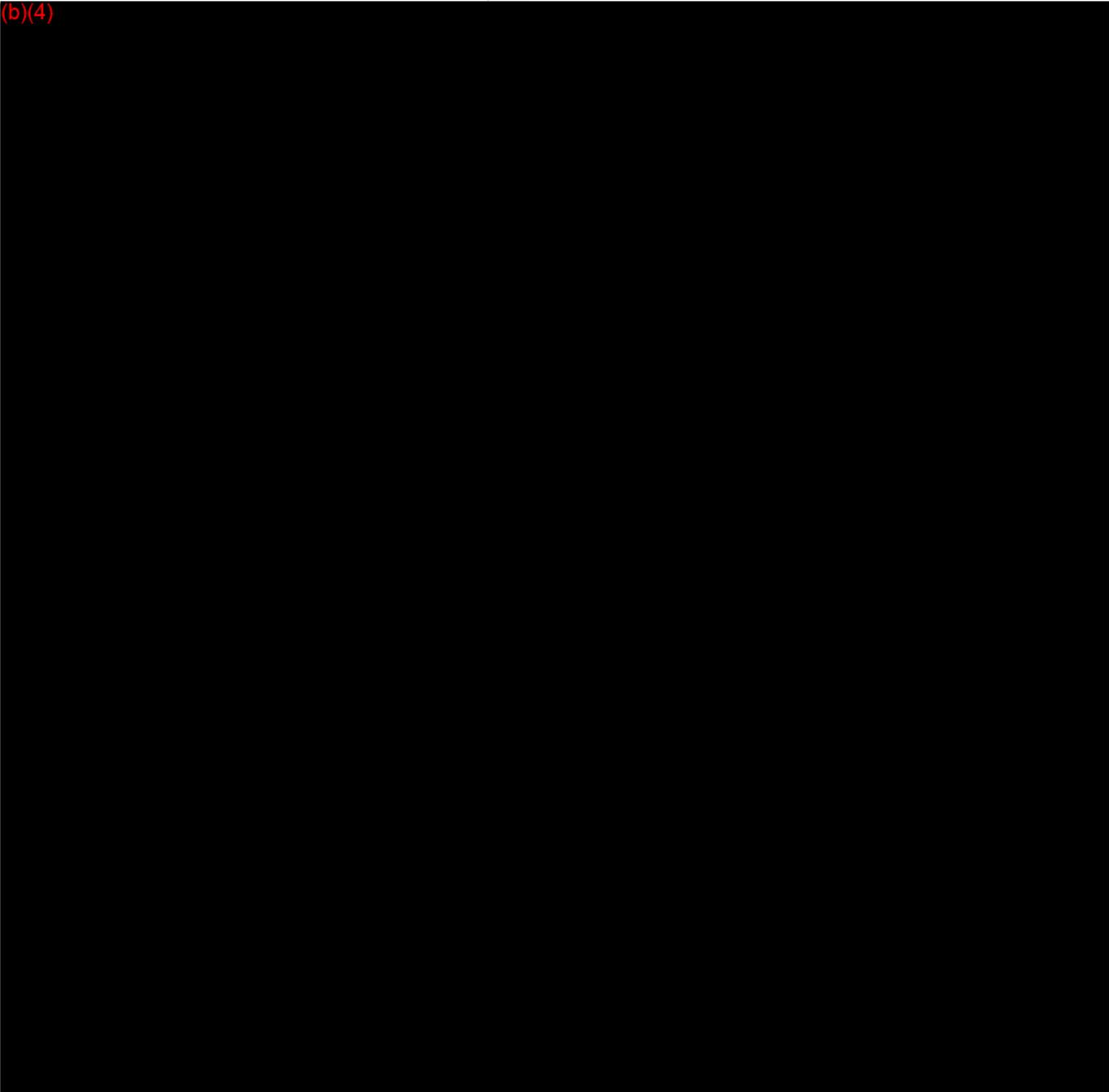
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(b)(4)

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**TEST METHOD**

(b)(4)

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Tensile Test of Coil / Delivery (b)(4)

(b)(4)

Experimental Results

(b)(4)

Result Summary

(b)(4)

Conclusion

(b)(4)

**STUDY TITLE:**

(b)(4)

TENSILE TEST OF THE TORQUE WIRE TO BRAID SOLDER JOINT  
PROJECT # (b)(4)

**TEST ARTICLES:**

(b)(4)

**SUBMITTER:**

(b)(6)

VICKI PRESIDENT  
REGULATORY AFFAIRS  
COOK INCORPORATED  
925 S. CURRY PIKE  
BLOOMINGTON, IN 47402

**SUBMISSION DATE:**

10-1-99

**TESTED BY:**

(b)(6)

TESTING & RELIABILITY ENGINEER

(b)(6)

PRODUCT DEVELOPMENT ENGINEER  
COOK INCORPORATED  
925 S. CURRY PIKE  
BLOOMINGTON, IN 47402

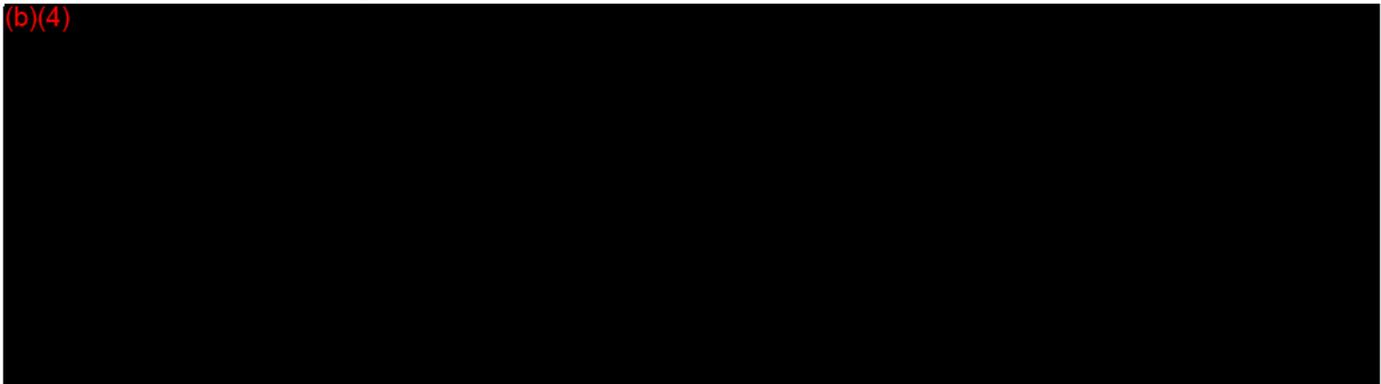
**PURPOSE OF THE TEST**

(b)(4)

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**GENERAL DESCRIPTION OF THE TEST**

(b)(4)

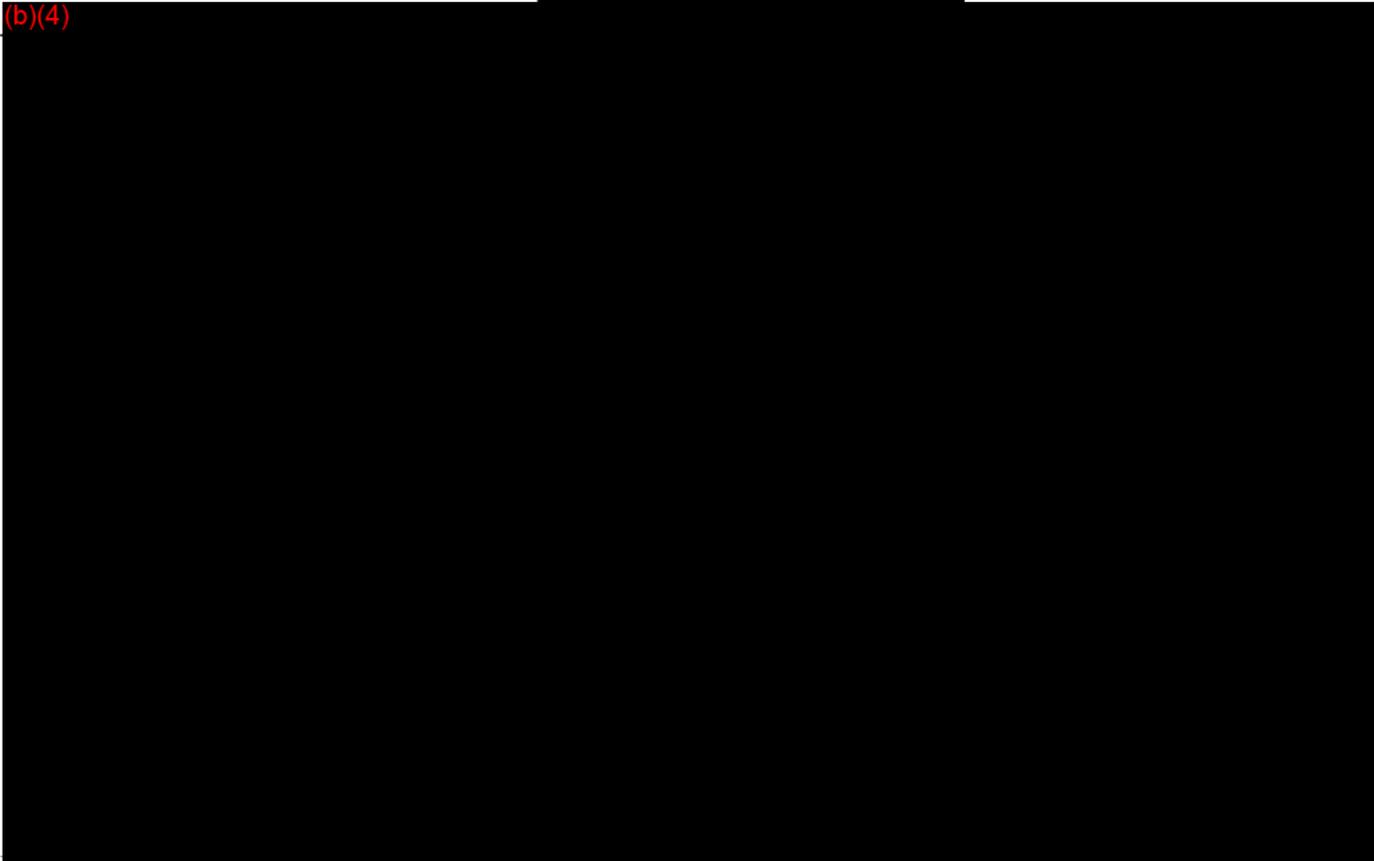
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**TEST METHOD**

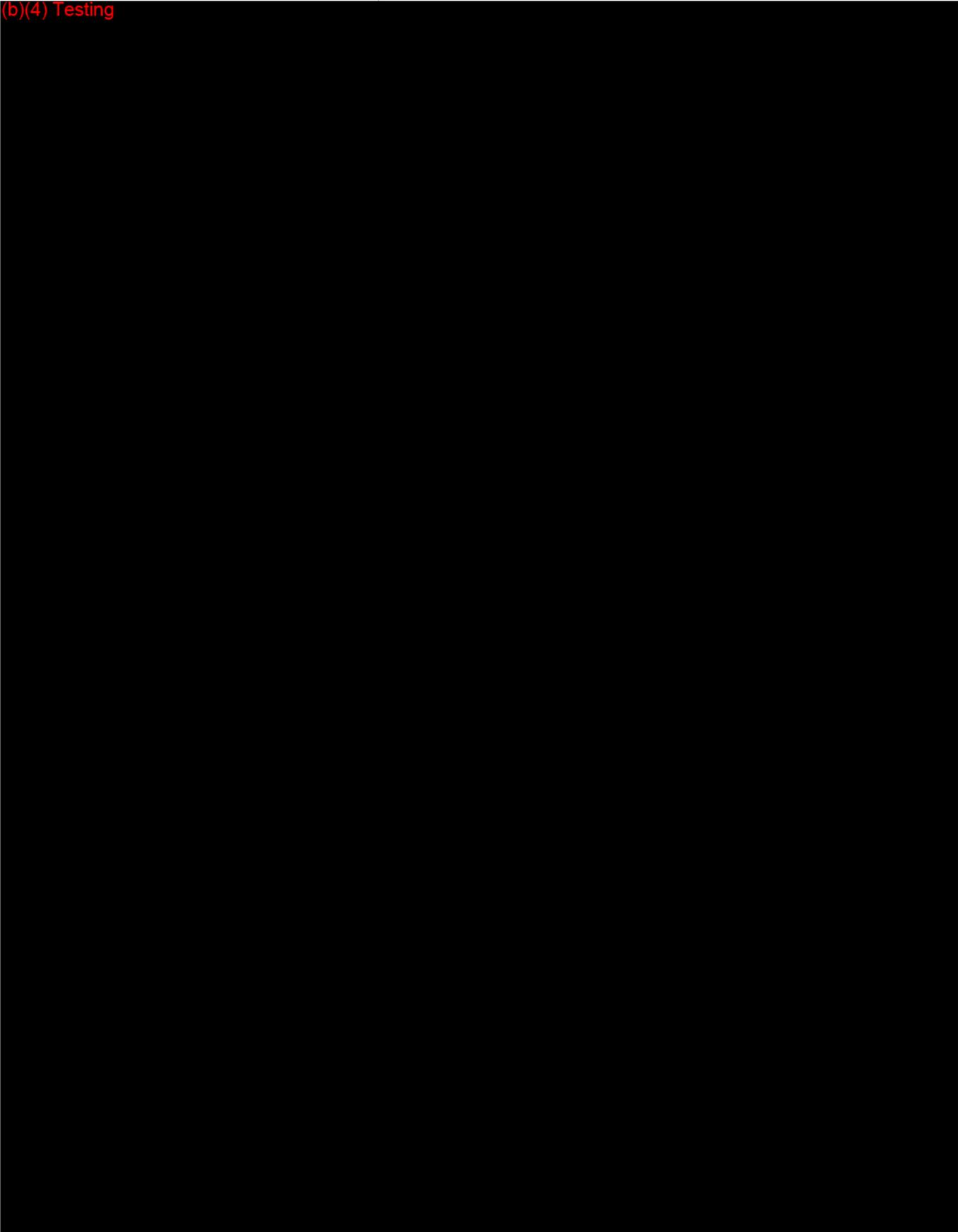
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(b)(4)

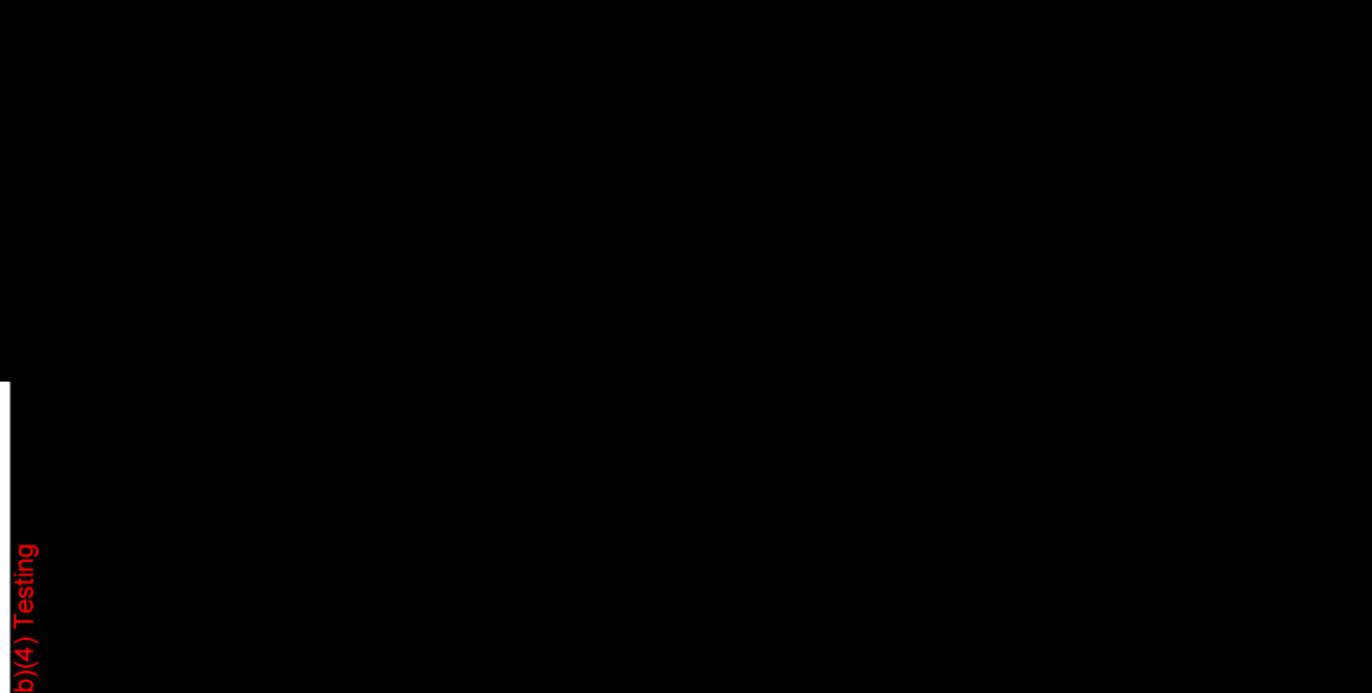
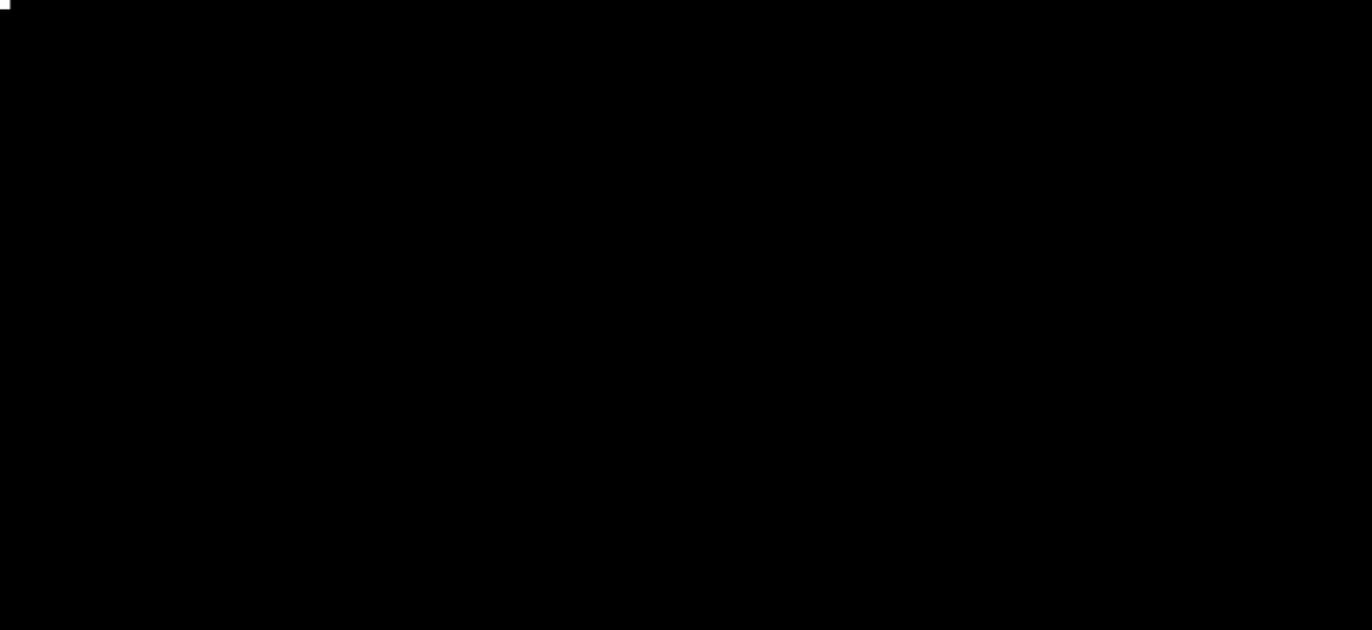
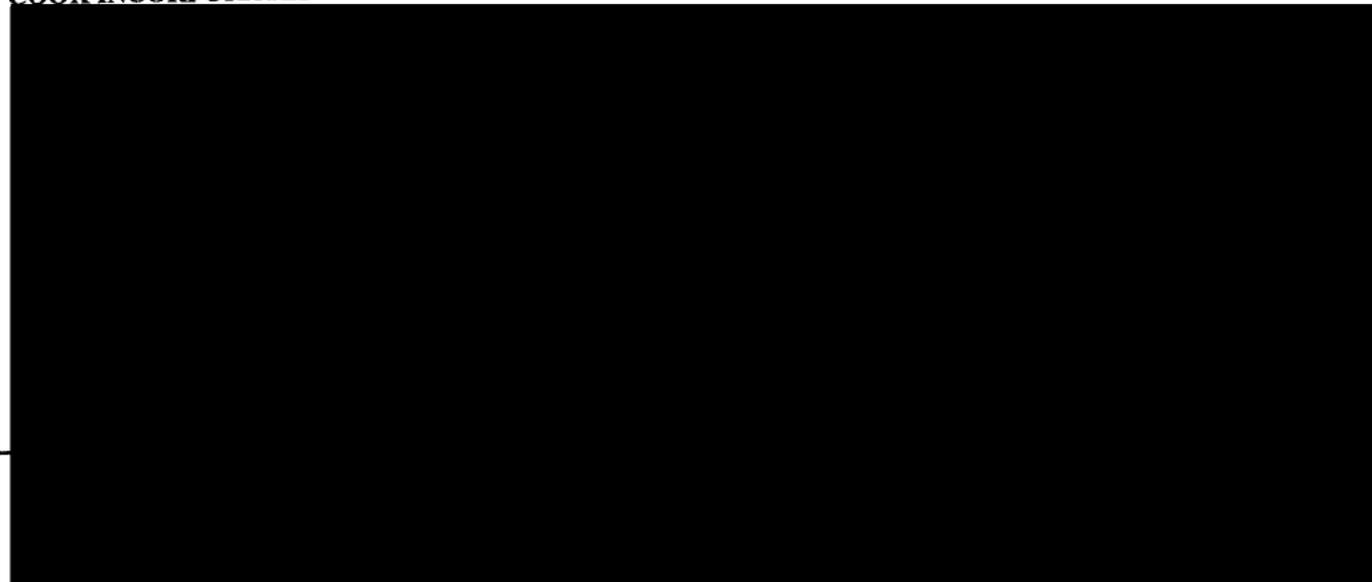
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(b)(4) Testing



**510(k) Premarket Notification**  
**Flipper™ Detachable Embolization Coil**  
**COOK INCORPORATED**

Trisile Test



(b)(4)

(b)(4) Testing

(b)(4)

(b)(4) Testing

**Result Summary**

(b)(4) Testing



Conclusion

(b)(4) Testing



CONFIDENTIAL

**ATTACHMENT 5**  
**BIOCOMPATIBILITY INFORMATION**

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**Flipper™ Detachable Embolization Coil**  
**COOK INCORPORATED**

**Biocompatibility Information**

The firm has extensive biocompatibility data which supports the material's suitability for use in these medical devices. The biocompatibility tests which have been performed adhere to the requirements listed in the *International Standard ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests*. The test requirements for the coils, which are categorized as permanent implant with a contact duration of > 30 days, include the following.

(b)(4)

Test Performed	Test Number	Test Results
----------------	-------------	--------------

(b)(4)

Test Performed	Test Number	Test Results
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(b)(4)

The test results provide assurance these materials are nontoxic and suitable for use in medical devices.

**SYNTHETIC FIBER** (b)(4)

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**ATTACHMENT 6**  
**PACKAGING AND STERILIZATION**

**Flipper™ Detachable Embolization Coil**  
**COOK INCORPORATED**

**Packaging**

The Flipper™ Detachable Embolization Coil is supplied sterile and is intended for one-time use. It will be packaged in a (b)(4) pouch. These packaging materials are currently used for other COOK products in commercial distribution. Testing of these packaging materials has been performed. The packaging configuration and the material provides an acceptable bacterial barrier and 3 years is an appropriate sterility expiration period.

**Sterilization**

The Flipper™ Detachable Embolization Coil will be sterilized using an (b)(4) (b)(4). The methods used to validate the sterilization cycle are described in the (b)(4) (b)(4)

(b)(4)

The sterilization process which will be used for the Flipper™ Detachable Embolization Coil is the same as that used for other COOK devices currently in commercial distribution.

**Pyrogen**

COOK INCORPORATED does not label devices "Pyrogen Free". (b)(4) assures apyrogenicity of medical devices based upon Good Manufacturing Practice and Quality Systems which ensure low microbial levels (bioburden) on the product.

(b)(4)

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**ATTACHMENT 7**

**510(K) SAFETY AND EFFECTIVENESS INFORMATION**

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**Safety and Effectiveness Information**

**Submitted By:** Karen Bradburn  
Regulatory Affairs Coordinator  
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**Device:** Flipper™ Detachable Embolization Coil  
Device, Embolization, Arterial (79KRD)  
21 C.F.R. Part 870.3300

**Predicate Devices**

The Flipper™ Detachable Embolization Coil is similar in terms of intended use, materials of construction and technological characteristics to the predicate devices reviewed: Embolization Coil Positioner Set, Hilal Embolization Microcoils, Vascular Occlusion System, Guglielmi Detachable Coil and Fibered Platinum Coil.

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**Device Description**

The Flipper™ Detachable Embolization Coil is used for arterial and venous embolization for the peripheral vasculature. This device is used in conjunction with the Flipper Detachable Coil Delivery Wire. The detachable coil delivery system provides safe delivery of embolization coils where the size of embolization coil is difficult to predetermine. A handle facilitates manipulation and provides safe and easy detachment of embolization coils. This device is provided sterile and is intended for one-time use.

The Flipper™ Detachable Embolization Coil consists of the embolization coils and the delivery wire. The embolization coils are manufactured using stainless steel wire with synthetic fibers. The delivery wire is manufactured using stainless steel with TFE coating. The device will be available in the following sizes and is compatible with catheters of 80 and 110 cm lengths.

Delivery Wire Diameter	0.035"
Extended Embolus Diameter	0.035"
Coil Length	3cm, 4cm, 5cm, 6cm, 8cm, 10cm, 12cm
Coil Embolus Diameter	3mm, 5mm, 6.5mm, 8mm

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## Substantial Equivalence

The Flipper™ Detachable Embolization Coil is similar to many devices already in commercial distribution for arterial and venous embolization. These devices include an Embolization Coil Positioner Set (Cook Incorporated), Hilal Embolization Microcoils (Cook Incorporated), the Vascular Occlusion System (Cordis Endovascular Systems Inc.), the Guglielmi Detachable Coil (Target Therapeutics) and a Fibered Platinum Coil (Target Therapeutics). All devices are introduced via the percutaneous method of entry using a catheter or microcatheter introducer.

The Embolization Coil Positioner Set was reviewed as substantially equivalent under D.C. K940189 and is indicated for arterial and venous embolization. The device is constructed of stainless steel and synthetic fiber with a coil wire diameter of 0.018 to 0.038 inches. The coils are available in straight or curled shapes with an emboli size range of 2 to 20 mm. A push-button release mechanism is the method of deployment.

Hilal Embolization Microcoils were reviewed as substantially equivalent under D.C. K901337 and are indicated for the embolization of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.018 inches. The coils are available in straight and curled shapes with an emboli size range of 3 to 10 mm. Deployment is achieved by a wire guide which pushes the coil out of the catheter.

The Vascular Occlusion System was reviewed as substantially equivalent under D.C. K983483 and may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. It is intended for the interventional radiologic management of arteriovenous malformation, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord and spine. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.014 inches. The coils are available in straight, "C", flat spiral and complex shapes with an emboli size range of 2 to 10 mm. Deployment is achieved by a wire guide which pushes the coils out of the microcatheter.

The Guglielmi Detachable Coil was reviewed as substantially equivalent under D.C. K951256, K960705 and K962503 and is indicated for embolization of intracranial aneurysms, arteriovenous malformations, arteriovenous fistulae and arterial venous embolizations in the peripheral vasculature. The device is constructed of platinum with a coil wire diameter of 0.010 to 0.018 inches. The coils are available in a helical shape with an emboli size range of 2 to 20 mm. The coils are deployed by electrolytic detachment from the wire guide.

The Fibered Platinum coil was reviewed as substantially equivalent under D.C. K955293 and is indicated for arterial and venous embolization in the peripheral vasculature. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.010 to 0.035 inches. The coils are available in the following shapes: straight, C-shaped, helical and complex helical. The emboli size range is 2 to 30 mm. Deployment is achieved by a wire guide which pushes the coil out of the catheter.

The Flipper™ Detachable Embolization Coil will be indicated for arterial and venous embolization for the peripheral vasculature. The delivery wire will be constructed of stainless steel with a diameter of 0.035 inches. The stainless steel coils with synthetic fiber will be available in curled shapes with an coil embolus diameter range of 3 to 8 mm. The coil is deployed when interlocking threads between the coils and the delivery wire are unscrewed.

#### Performance Data

The following tests have been performed to evaluate the ability of the Flipper Detachable Embolization Coil to perform in accordance with the requirements of the design plan.

- ❖ *In-Vitro* Performance Test: Loading, Passage and Deployment
- ❖ Tensile Test: Coil Thread/Delivery System
- ❖ Tensile Test: Torque Wire to Braid Soft Joint

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use for arterial and venous embolization in the peripheral vasculature.

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**ATTACHMENT 8**

**TRUTHFUL AND ACCURATE STATEMENT**

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**Premarket Notification Truthful and Accurate Statement**  
**(as required by 21 CFR 807.87(j))**

I certify that, in my capacity as a writer and submitter of this document on behalf of COOK INCORPORATED, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Karen Bradburn  
Karen Bradburn  
Regulatory Affairs Coordinator

10-8-99  
Date

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**ATTACHMENT 9**  
**CLASS III CERTIFICATION AND SUMMARY**

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**Class III Certification Statement**  
**(as required by 21 CFR 807.94)**

I certify, in my capacity of as writer and submitter of this document on behalf of COOK INCORPORATED, that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the Flipper™ Detachable Embolization Coil, subject of this submission. I further certify that I am aware of the types of problems to which the Flipper™ Detachable Embolization Coil is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the Flipper™ Detachable Embolization Coil is complete and accurate.

Karen Bradburn  
Karen Bradburn  
Regulatory Affairs Coordinator

10-8-99  
Date

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## CLASS III SUMMARY

### I. DESCRIPTION OF ARTERIAL EMBOLIZATION DEVICES

The arterial embolization devices manufactured and marketed in the U.S. by COOK INCORPORATED consist of platinum wire coils with synthetic material attached and stainless steel coils with synthetic material attached. The coils, supplied sterile and individually packaged, are available in various straight and curled configurations, with a nominal coil diameter of .018 inches, nominal lengths ranging from 0.5 to 7 cm, and nominal curl diameters ranging from 2 to 10 mm. These COOK INCORPORATED embolization devices are used for arterial and venous embolization and embolization of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine.

### II. RISKS TO HEALTH POSED BY ARTERIAL EMBOLIZATION DEVICES

The long history of use of arterial embolization devices and the large number of published clinical reports show that the potential risks related to this type of device are well known and extensively documented. The following table summarizes these associated risks, typical causes, and corresponding recommendations for minimizing their occurrence. Knowledge of these potential risks and associated recommendations may be incorporated in labeling guidance for arterial embolization devices to serve as a special control. The information summarized in the following table is based on scientific publications covering a span of clinical use of arterial embolization devices of

more than 20 years (18 articles dating from 1989 to 1997). Please refer to Section III  
of this submission for text summarizing this information.

**SUMMARY OF POTENTIAL RISKS OF ARTERIAL EMBOLIZATION DEVICES**

PROBLEM	CAUSE	COMMENT	REF.
Transient Neurologic Deficit	<ul style="list-style-type: none"> <li>Inadequate perfusion as result of embolization</li> <li>Expected response due to vessel occlusion, tissue infarction, and trauma of procedure</li> <li>Manipulation of eloquent area</li> <li>Thromboembolism in normal cerebral arteries due to distal migration of intra-aneurysmal thrombus</li> </ul>	<ul style="list-style-type: none"> <li>Expected complications of neurovascular embolization</li> <li>Use careful technique and closely monitor patient; advise patient of this potential side effect</li> <li>Perioperative management of fibrinolytic and coagulation activity will minimize thromboembolic complications</li> </ul>	3, 7, 8, 11, 12, 13
Permanent Neurologic Deficit	<ul style="list-style-type: none"> <li>Inadequate perfusion as result of embolization</li> <li>Manipulation of eloquent area</li> </ul>	<ul style="list-style-type: none"> <li>Expected complication of neurovascular embolization</li> </ul>	1-4, 7, 8, 9, 14
Infarction, Tissue Ischemia, Necrosis	<ul style="list-style-type: none"> <li>Expected response due to vessel occlusion and tissue infarction</li> <li>Inadvertent embolization into wrong vessel</li> <li>Use of inappropriate size/amount of embolus material</li> <li>Reflux during placement</li> <li>Use of inappropriate catheter</li> <li>Introduction under high-flow conditions</li> <li>Excessive vessel tortuosity</li> <li>Inadequate perfusion</li> </ul>	<ul style="list-style-type: none"> <li>Incidence may be greater in patients presenting with ruptured aneurysm</li> <li>Carefully select embolus size/amount for target vessel</li> <li>Use careful catheter technique</li> <li>Use superselective catheterization</li> <li>Conduct careful, continuous hemodynamic monitoring and tissue response to the embolic material delivered</li> <li>Use special care in high-flow conditions</li> <li>Achieve equilibrium between embolizing target area and avoiding ischemic necrosis of non-target areas</li> </ul>	2, 5, 8, 14, 15

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PROBLEM	CAUSE	COMMENT	REF.
Pseudoaneurysm Formation	<ul style="list-style-type: none"> <li>Result of embolization treatment of traumatic artery lesions</li> <li>May develop from collateral flow</li> </ul>	<ul style="list-style-type: none"> <li>Consider collateral blood supply</li> <li>Use low pressure delivery system</li> <li>Use proximal and distal occlusion to prevent retrograde filling of a lesion</li> </ul>	14, 15
Incomplete Occlusion	<ul style="list-style-type: none"> <li>Embolus material placed too proximally</li> <li>Development of collateral flow</li> <li>Excessive vessel tortuosity</li> </ul>	<ul style="list-style-type: none"> <li>Consider collateral blood supply</li> <li>Embolize distally to allow for supplemental embolization, if necessary</li> </ul>	3, 5, 7, 10
Hemorrhage	<ul style="list-style-type: none"> <li>Vasospasm</li> <li>Occlusion of main venous drainage</li> <li>Achievement of only partial occlusion of malformation</li> <li>Burst of embolic balloon and concomitant dissection of feeding vessel</li> <li>Aneurysm perforation or rupture</li> </ul>	<ul style="list-style-type: none"> <li>Use careful catheter technique</li> <li>Conduct careful, continuous hemodynamic monitoring</li> <li>Avoid using large artificial emboli in small vessel or aneurysm</li> </ul>	4, 5, 6, 8, 15
Death	<ul style="list-style-type: none"> <li>Result of complications of subarachnoid hemorrhage</li> <li>Aneurysm rupture</li> <li>Pulmonary complications</li> <li>Reflux of emboli</li> <li>Cerebral infarction from displaced emboli</li> </ul>	<ul style="list-style-type: none"> <li>Technical complications commonly occur in this high risk patient population</li> <li>Use meticulous technique</li> <li>Conduct careful, continuous hemodynamic monitoring throughout and immediately following the procedure</li> </ul>	6, 7, 8, 9, 15

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### III. SUMMARY OF VALID SCIENTIFIC EVIDENCE

Since the 1960's, a wealth of clinical experience on transcatheter arterial embolization has been reported for the treatment and management of tumors, hemorrhage, and vascular malformations (aneurysms, arteriovenous fistulas, and other vascular lesions). The embolization materials described have included autologous tissue, clot, and thrombin mixtures, Gelfoam, wool, cotton, tantalum powder, silicone preparations, sclerosing agents (e.g., Ethibloc), instantly setting polymers (e.g., isobutyl-2-cyanoacrylate), metallic, glass and plastic spheres, polyvinyl alcohol, radioactive particles, intravascular balloons, and various configurations of metal springs or coils. Embolization has been performed prophylactically, as a preparatory step or adjunct to surgical treatment, or as an alternative to surgical treatment in the poor-risk patient. Because of the long historical experience of transcatheter embolization and the large number of clinical publishings, the information available is extensive. The feasibility and efficacy for use of these artificial embolization devices are shown in their long history of use and the successful clinical results. The following summarizes the potential associated risks which have been noted in the preceding table (Section II of this summary) with recommendations for minimizing their occurrence, supporting the premise that sufficient information exists to establish special controls to provide reasonable assurance of safe and effective use.

A well-documented risk associated with arterial embolization devices is that of neurologic deficit, which may be transient or permanent.<sup>1, 2, 3, 4, 7-9, 11, 12, 13, 14</sup> This is an expected response due to inadequate perfusion when performing embolization,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118  
procedure trauma, and manipulation of eloquent areas. This complication has been

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attributed to thromboembolism which may result from distal migration of intra-aneurysmal thrombus during the procedure. To minimize the occurrence and severity of neurologic deficits, it is important that the procedure be performed with extreme care, to closely monitor the patient, use perioperative management of fibrinolytic and coagulation activity, and to inform the patient of this expected risk.

Another common risk associated with arterial embolization devices is the inadvertent embolization of a vessel and/or tissue which may result in unintentional tissue ischemia, infarction/stroke, and tissue necrosis.<sup>2, 5, 8, 14, 15</sup> Ischemia leading to some degree of tissue injury in the embolized circulation may occur to a varying degree in all embolization procedures. Although the frequency of inadvertent embolization is believed to be related to the experience and expertise of the interventional radiologist, several authors have offered specific recommendations to minimize the potential for this problem to occur under various clinical conditions. It is of utmost importance to use the appropriate size embolus (or appropriate amount of embolic material). Meticulous catheter technique is advised, with continuous hemodynamic monitoring and evaluation of tissue response to the embolization. Since flow patterns in the embolization region may change rapidly during injection of emboli, care must be taken to preclude reflux of emboli into vessels serving normal areas. The goal is to achieve equilibrium by embolizing the targeted area and avoiding ischemic necrosis of non-target areas. It has been noted that the incidence may be greater in patients presenting with ruptured aneurysms.

The formation of an aneurysm or pseudo-aneurysm related to arterial  
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118  
embolization has been noted to occur.<sup>14, 15</sup> Formation may be a result of embolization

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treatment of traumatic artery lesions, or may develop from collateral blood flow after embolization. To preclude aneurysm formation, the collateral blood supply should be evaluated, and proximal and distal occlusion using a low pressure delivery system should be employed when clinically indicated.

Incomplete occlusion of the targeted site is a well known complication.<sup>3, 5, 7, 10</sup> It is important to be aware of the tortuosity of the targeted vessels, to embolize distally, and to consider the potential for the development of collateral blood flow to the targeted site.

Another serious complication associated with arterial embolization procedures is hemorrhage due to severe vasospasm, occlusion of main venous drainage, achieving only partial occlusion of vessel malformation, and rupture or perforation or aneurysm of the vessel due to trauma of procedure.<sup>4, 5, 6, 8, 15</sup> Occurrence may be minimized using careful catheter technique, being aware of excessive vessel tortuosity, and avoiding the use of large emboli (or embolic media) in a small vessel or aneurysm.

Death is a known complication in this high-risk patient population. Death may be attributed to subarachnoid hemorrhage, aneurysm rupture, pulmonary complications, and cerebral infarction from displaced or refluxed embolic material.<sup>6-9, 15</sup> In all embolization procedures, meticulous technique is essential, along with careful continuous hemodynamic monitoring throughout and immediately following the procedure.

In summary, the potential and reported risks associated with arterial embolization devices and placement procedures are well known and extensively

documented. These risks may be minimized under the use of radiologists experienced

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in interventional techniques, by using careful catheter technique, by monitoring tissue response to embolization during and after the procedure, and by continuous patient monitoring to provide awareness for the described potential and reported complications. The use of arterial embolization devices has been documented for more than thirty years. The numerous scientific articles which exist describing clinical experience with this type of device support its suitability for the intended use. Reasonable assurance of safe and effective use of these devices is demonstrated through: extensive clinical experience with the device, the reported complication rates, and the well-documented instructional information which is available regarding the known potential complications associated with device use and how to minimize them. This information may be incorporated in device labeling guidance, serving as a special control to support reasonable assurance of safety and effectiveness.

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