

K 940189

NOV 28 1994

510 (K) PREMARKET NOTIFICATION

SAFETY AND EFFECTIVENESS INFORMATION AS REQUIRED UNDER § 513 (i)(3)(A)

Submitted by:

**COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402**

Phone: 1-800-346-2686

Premarket Notification
Coil Positioner Set

Certification

I certify that a reasonable search of information known or otherwise available to me has been conducted about the types and causes of safety and/or effectiveness problems that have been reported for arterial embolization devices. I further certify that I am aware of the types of problems to which arterial embolization devices are susceptible and that the following summary of the types and causes of safety and/or effectiveness problems about arterial embolization devices is reasonably complete and accurate to the best of my knowledge. From the search conducted under my direction, the following information summarizes substantial equivalence and safety and effectiveness information associated with arterial embolization devices and provides the literature citations upon which this summary is based.

Prepared By

Submitter's Name.....COOK INCORPORATED
Address.....925 S. Curry Pike, P.O. Box 489
.....Bloomington, Indiana 47402
Phone Number.....812-339-2235 or 800-346-2686
Contact Person.....April Lavender, Mgr. Regulatory Affairs
Signature.....April Lavender
Date of Summary.....January 12, 1994

Name of Device

Trade Name.....None Established
Common Usual Name....Coil Positioner Set
Classification Name..Arterial Embolization Device

Name of Predicate or Legally Marketed Comparison

<u>Name of Device</u>	<u>Manufactured By</u>
Embolization Coils and GAO Set	COOK INCORPORATED Bloomington, Indiana
Embolization Coils and Delivery System	Target Therapeutics San Jose, California

Describe the Device

Function

The device, subject of this submission, is intended to function in an identical manner to the pre-Amendment coils and the predicate coils to which it is compared to as shown above. The device, subject of this submission, is comprised of components which are already being legally marketed by COOK INCORPORATED. The purpose of this 510(k) notification is to describe a set system which will be supplied sterile and preassembled that will be used to deliver the coil to its desired vascular destination.

Basic Scientific Concept

The basic scientific concept of the component assembly, subject of this submission, relates to a modification in the components' design which will allow the coil to be deployed with a release mechanism controlled by the physician. This development in the COOK product family of occlusion devices is substantially equivalent to the Target Therapeutics selective vascular occlusion system(s). Like the Coil Positioner Set, these competitive devices are selectively deployed with catheter systems that are provided specifically for coil deployment.

Device Design

The device design was developed to accommodate the standard coil material and configuration, a modified wire guide and a low profile TFE delivery catheter with proximal push-button. The coil remains attached to the distal tip of

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Coil Positioner Set

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the wire guide and remains housed in the TFE catheter until the desired time of deployment. At the time of desired coil deployment, the physician depresses the proximal handle to advance the coil out of the end of the catheter.

Physical properties of the device, subject of this submission, are identical to the legally marketed pre-Amendment and predicate devices mentioned above. The combination of these devices into a Coil Positioner Set does not significantly change any of their physical properties.

Indications for Use

This device is indicated in any patient with a medical need for a percutaneous transcatheter vascular occlusion procedure.

Summary of Safety/Effectiveness Problems

Since the 1960's, transcatheter arterial embolization has been reported for the treatment and management of tumors, hemorrhage, and vascular malformations (aneurysms, arteriovenous fistulas, angiomas). Embolization materials have included autologous tissue and clot, thrombin mixtures, Gelfoam, wool, cotton, metallic and plastic spheres, tantalum powder, silicone preparations, instantly setting polymers such as isobutyl 2-cyanoacrylate, radioactive particles, intravascular balloons, Ivalon plugs, and metal springs or coils. Embolization procedures have been performed prophylactically, as an adjunct to surgical treatment, or as an alternative to surgical treatment in the poor-risk patient. We have provided the following information to

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Coil Positioner Set**

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summarize the types and causes of reported safety and/or effectiveness problems with all types of embolization devices as well as adverse safety and effectiveness data, i.e., problems to which these types of predicate devices are susceptible and the potential causes of such problems.

This summary includes a review of 21 published articles dating from 1976 to 1993. The feasibility and efficacy for the use of the COOK Coil Positioner Set can be shown by the widespread history of coil use and successful clinical results associated with coil embolization devices. Please refer to the summary table and bibliography which follow.

SUMMARY TABLE
TYPES AND CAUSES OF SAFETY AND/OR EFFECTIVENESS PROBLEMS OF ARTERIAL EMBOLIZATION COILS

PROBLEM	CAUSE	COMMENT	REF.
Post-Embolism Syndrome (localized pain, fever, transient hypertension, leucocytosis, hematuria, nausea, vomiting, ileus)	<ul style="list-style-type: none"> •Expected response due to vessel occlusion and tissue infarction 	<ul style="list-style-type: none"> •Symptoms usually subside within 12 to 96 hours, are typically mild, and may be minimized using narcotics and antipyretics 	1-4,6,8,11,13,14,16,18,21
Inadvertent Embolization and/or Misplaced Coils	<ul style="list-style-type: none"> •Use of inappropriate size coil •Reflux during placement •Passage through large AV shunts •Displacement during subsequent surgery •Extrusion of coil from catheter tip •Use of inappropriate catheter •Introduction under high-flow conditions •Excessive vessel tortuosity 	<ul style="list-style-type: none"> •Carefully select coil size for target vessel •Use careful catheter technique and sequential embolization with intermittent filming •Use customized introducing catheter •Use appropriate amount of embolic material •Conduct careful, continuous hemodynamic monitoring •Use special care in high-flow conditions •Achieve equilibrium between embolizing target area and avoiding ischemic necrosis of non-target areas 	1-13,16,17,19-21
Thromboembolism	<ul style="list-style-type: none"> •Typical complication related to angiography procedure •Retrograde propagation of thrombus from embolized artery •Stripping of adherent thrombus from introducing catheter during catheter removal •Vessel trauma 	<ul style="list-style-type: none"> •Use systemic heparinization, if necessary •Use careful catheter technique 	1-4,21
Renal Failure	<ul style="list-style-type: none"> •May result from renal tumor infarction •Possibly related to use of excess contrast agent 	<ul style="list-style-type: none"> •Avoid use of excess contrast agent by performing diagnostic and therapeutic procedures on separate days •Immediately analyze/monitor kidney function 	1-3,6
Large Renal Volume Loss	<ul style="list-style-type: none"> •General vessel embolization (vs. specific) •Multiple embolizations performed •Incorrect proximal coil placement 	<ul style="list-style-type: none"> •Conduct careful search for specific bleeding branch prior to embolization •Avoid multiple embolizations, if possible •Perform distal occlusion, if possible 	13,16
Prolonged Hypertension	<ul style="list-style-type: none"> •Renal tissue ischemia may cause release of renal plasma renin 	<ul style="list-style-type: none"> •Consider hematologic status of patient •Immediately analyze function of other kidney for inadvertent embolization 	6
Post-Infarction Abscess	<ul style="list-style-type: none"> •May result from infarcted tissue •Immunosuppressed patient more susceptible 	<ul style="list-style-type: none"> •Use careful sterile techniques and possible antibiotic coverage •Monitor tissue response to embolism 	1-4,6

Premarket Notification
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SUMMARY TABLE (CONTINUED)

PROBLEM	CAUSE	COMMENT	REF.
Aneurysm or Pseudo-Aneurysm Formation	<ul style="list-style-type: none"> •May develop from collateral flow •Arterial puncture site susceptible 	<ul style="list-style-type: none"> •Consider collateral blood supply •Use low pressure delivery system •Use proximal and distal occlusion to prevent retrograde filling of a lesion 	6,15,18,21
Incomplete Occlusion	<ul style="list-style-type: none"> •Coil lodges in catheter, preventing placement •Coil(s) placed too proximally •Development of collateral flow •Excessive vessel tortuosity 	<ul style="list-style-type: none"> •Consider collateral blood supply •Embolize distally to allow for supplemental embolization, if necessary 	7,15,18,21
Hemorrhage	<ul style="list-style-type: none"> •Vessel or aneurysm wall perforation or rupture by guide wire, catheter or device 	<ul style="list-style-type: none"> •Use careful catheter technique •Conduct careful, continuous hemodynamic monitoring 	8,19,20
Intimal Dissection	<ul style="list-style-type: none"> •Excessive vessel tortuosity •Use of inappropriate catheter or guide wire 	<ul style="list-style-type: none"> •Use careful catheter technique with appropriate size coils 	16,21
Congestive Heart Failure	<ul style="list-style-type: none"> •Overzealous administration of fluids, blood, and components 	<ul style="list-style-type: none"> •Conduct careful, continuous hemodynamic monitoring 	9
Dysphagia	<ul style="list-style-type: none"> •Embolization of distal esophageal arterial branches 	<ul style="list-style-type: none"> •Use careful catheter technique •Conduct careful, continuous hemodynamic monitoring 	18
Contrast Extravasation	<ul style="list-style-type: none"> •Not specified 	<ul style="list-style-type: none"> •Use careful catheter technique 	16
Massive Release of Humoral Substances	<ul style="list-style-type: none"> •"Theoretical" complication possibly related to infarction of endocrine tissues 	<ul style="list-style-type: none"> •Monitor tissue response to embolism 	4

Premarket Notification
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BIBLIOGRAPHY

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NOV 28 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Ms. April Lavender
Manager, Regulatory Affairs
Cook Incorporated
925. South Curry Pike P.O. Box 489
Bloomington, Indiana 47402

Re: K940189
Coil Positioner Set
Regulatory Class: III
Dated: May 19, 1994
Received: May 20, 1994
Product Code: KRD

Dear Ms. Lavender:

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 to 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 for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) 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.

Sincerely yours,



Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



510(k) NUMBER K940189 PANEL CV DIVISION DCRND BRANCH

TRADE NAME COIL POSITIONER SET

COMMON NAME COIL POSITIONER SET

PRODUCT CODE _____

CLASS
III

APPLICANT COOK INCORPORATED

SHORT NAME COOK

CONTACT APRIL LAVENDER

DIVISION _____

ADDRESS 925 SOUTH CURRY PIKE

P.O. BOX 489

BLOOMINGTON, IN 47402

PHONE NO. (812) 339-2235

FAX NO. (812) 339-5369

MANUFACTURER COOK INCORPORATED

REGISTRATION NO. _____

DATE ON SUBMISSION 12-JAN-94

DATE DUE TO 510(K) STAFF 29-MAR-94

DATE RECEIVED IN ODE 13-JAN-94

DATE DECISION DUE 13-APR-94

DECISION _____

DECISION DATE NOV 28 1994

SUPPLEMENTS SUBMITTED RECEIVED DUE POS DUE OUT

S001 19-MAY-94 20-MAY-94 03 AUG 94 18-AUG-94

CORRESPONDENCE SENT DUE BACK

C001 12-APR-94 12-JUN-94 HOLD LETTER

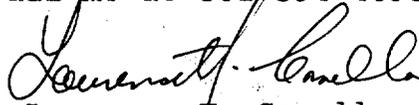
SE 8/30/94

B

DATE 23-NOV-94
FROM FIELD PROGRAMS BRANCH, CDRH, HFZ-331
JECT "PROCEED" FOR CLASS III, 510(k): K940189
T See Below

Based on the district's response regarding the GMP compliance status of the 510(k) device manufacturer(s) below, we recommend that the 510(k) submission proceed.

If you have any questions, please call me at 301-594-4695.


Lawrence H. Comella

510(k): K940189
Product: COIL POSITIONER SET
Applicant: COOK INCORPORATED
925 SOUTH CURRY PIKE P.O. BOX 489
BLOOMINGTON, IN 47402

Sites:
DET (MFG/STRL) COOK INCORPORATED
925 SOUTH CURRY PIKE P.O. BOX 489
BLOOMINGTON, IN 47402
CFN: 0

HFZ-404 (ODE)
cc: HFR-MW200 (DET)



Memorandum

Date _____
 From REVIEWER(S) - NAME(S) Roy / Saperstein
 Subject 510(k) NOTIFICATION K940189/SI
 To THE RECORD

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

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes No

This 510(k) contains: (check appropriate box(es))

- A 510(k) summary of safety and effectiveness, or
- A 510(k) statement that safety and effectiveness information will be made available
- The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

KRD III

Additional Product Code(s) w/Panel (optional):

REVIEW A. DeWitt
(BRANCH CHIEF)

P020B 8/19/94
BRANCH CODE (DATE)

FINAL REVIEW: Kimberly Palmer
for (DIVISION DIRECTOR)

8/29/94
(DATE)

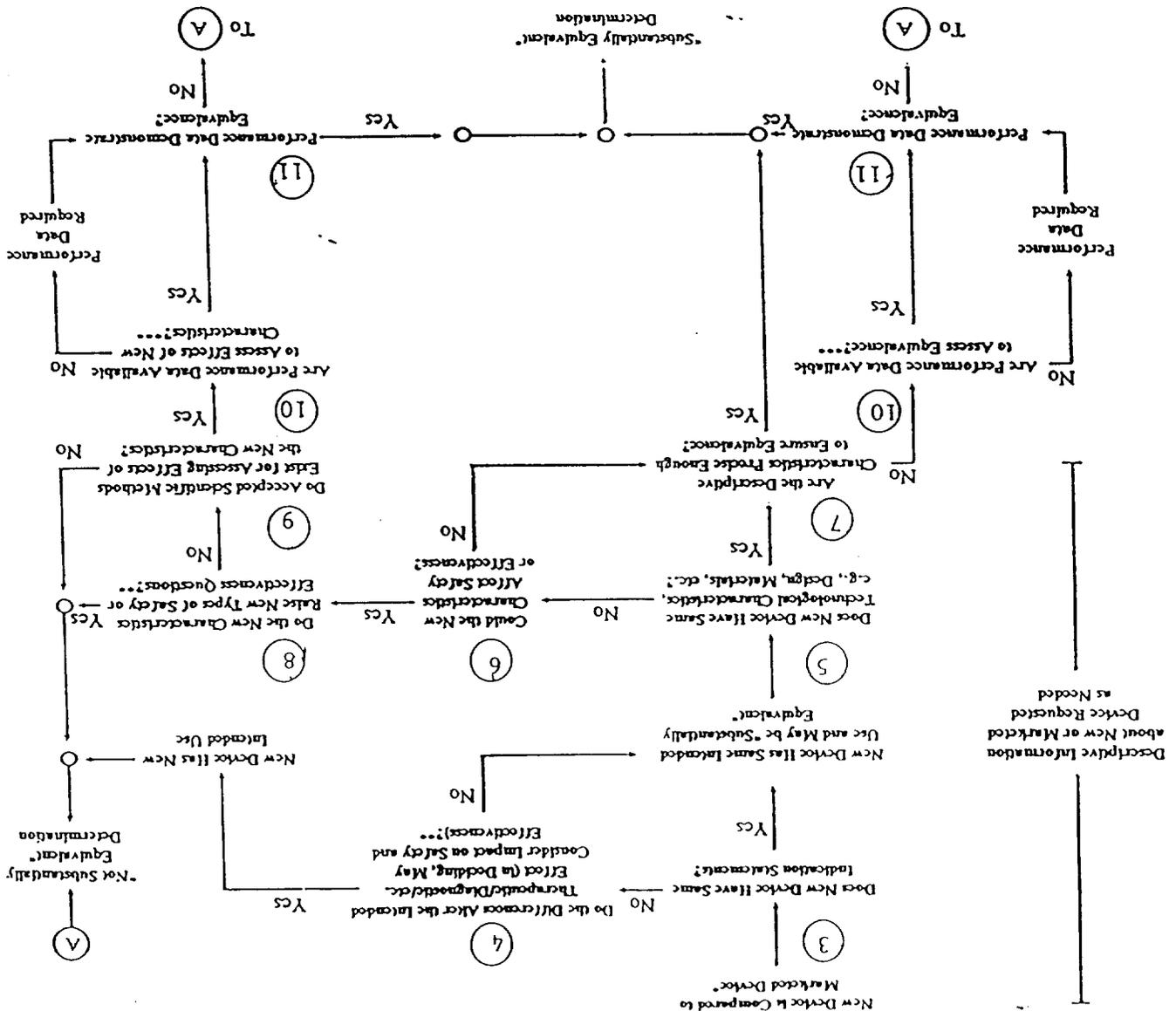
*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DECISION-MAKING PROCESS (DETAILED)

Questions? Contact FDA/CDRH at CDRH@FDA.gov or 301-796-8118



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear. This decision is normally based on descriptive information alone, but limited testing information is sometimes required. ... Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

**Division of Cardiovascular, Respiratory & Neurological Devices
Prosthetics Devices Branch**

MEMO

To: Ken Palmer, Ph.D. (HFZ-450)
From: Joydeb Roy (HFZ-450) *JR*
Date: August 29, 1994
Subject: K940189 (Coil Positioner Set) Tracking Issue

The above Coil Positioner Set device does not meet the statutory requirements for tracking under 21 CFR Part 821. Further, an MDR search has not produced either a whole lot of complications or any serious complications. Based on the above information, the device may not be tracked.

cc. Doyle A Gantt
cc. Jan Donelson

PROSTHETIC DEVICES BRANCH

REVIEW MEMORANDUM FOR FILE

FROM: JOYDEB ROY, Ph.D., (HFZ-450) *JR*
TO: File
REVIEW DATE: August 18, 1994 *[initials]*
DOCUMENT#: K940189/A
DEVICE: Coil Positioner Set
MANUFACTURER: Cook Incorporated
Distributor: Cook Incorporated
DOC. TYPE: Additional Information
DECISION/STATUS: SE
CONSULTING REV: Wolf Sapirstein, M.D.

RESPONSE TO DOYLE MEMO(8/18)

Cook Incorporated, the manufacturer of the subject device, has been marketing two other coil embolization devices (Embolization Set - Gianturco-Wallace-Anderson Arterial Embolization Set, & Embolization Coils - Hilal Embolization Microcoils, See Appendix H) for some time. These marketed (predicate) device(s) have been claimed to be substantially equivalent to the subject device. The predicate devices consist of a delivery catheter (physician selected), a guide wire and a coil. A standard angiographic catheter is used to position the coil. Percutaneous entry utilizing a Seldinger technique is used in the placement of the angiographic catheter. The angiographic catheter is then used to position the coil and its deployment. First, the angiographic catheter is placed in actual position, the cartridge containing the coil is then placed into base of hub of the angiographic catheter along with the wire guide and the delivery catheter, the wire guide is used to push the coil out of loading cartridge into catheter lumen and into final position. Appendix G & H contains some information on the predicate device(s) operation.

The Coil Positioner Set, subject of this application, however, comes with its own deployment catheter, and coil pre-loaded in the coil cartridge. The catheter, guide wire and coil are combined in the device. The components, (1) catheter and coil assembly, (2) guide wire/coil pusher, and (3) coil are shown in Appendix A (Figs. 1-3). The difference(s) between the predicate device(s) and the subject device is: coil- a gap has been added between the windings to position the distal tip of the guide wire; guide wire - guide wire distal end has a soldered tip to help with the positioning of the guide wire to the coil, and catheter - a push button switch added at the proximal end. The details of the device operation, which is similar to the operation of the predicate device(s) is diagrammed in Appendix A, Figs.4-8.

The angiographic catheter is first placed percutaneously at the selected location. The Coil Positioner Set with the pre-loaded coil cartridge, guide wire and delivery catheter is then placed at the base of hub of the proximal end of the pre-positioned angiographic catheter. Using fluoroscopy, the coil delivery (positioner) catheter is advanced until it reaches the distal tip of the pre-positioned angiographic catheter. The coil will remain attached to the coil positioner system during this maneuver and can be repositioned or withdrawn back into the

[Handwritten signature]

angiographic catheter, if required. After the coil is positioned, the safety lock is removed from the coil positioner catheter (see Appendix A, Fig.7). The proximal button on the coil positioner catheter is depressed to release the coil. After that the coil positioner catheter, guide wire and the loading cartridge is removed from the angiographic catheter.

The modifications made in the device is rather simple and does not change significantly the coil positioning and placement. The use of a switch at the proximal end of the positioner catheter does not change the method of deployment and placement of the coil compared to the predicate device, where the spring embolus introducer and pusher are used for that purpose. Pages 11-16 of the January submission provides some detail also.

The modifications instituted in the subject device have not affected the device safety and effectiveness. As to the concern regarding the release mechanism, the release mechanism will only release the coil when the physician will push the release button after he is sure that the coil is positioned properly.

I hope, this answers your questions.

Note: The 510k Program Operations Staff (POS) have not been able to locate a sample of the subject device supposed to have been mailed to us.



Memo Record

From: Chief, Prosthetic Devices Branch, HFZ-450

To: Joydeb Roy, Ph.D.

Date: August 18, 1994

Subject: K940189

=====
Your review memo dated August 10 is still incomplete.

... that you describe the exact
(b)(4)

(b)(4)

If you have any questions concerning this matter, please let me know.



A. Doyle Gantt

PROSTHETIC DEVICES BRANCH

REVIEW MEMORANDUM FOR FILE

FROM: JOYDEB ROY, Ph.D., (HFZ-450) JR
TO: File
REVIEW DATE: August 10, 1994
DOCUMENT#: K940189/A
DEVICE: Coil Positioner Set
MANUFACTURER: Cook Incorporated
Distributor: Cook Incorporated
DOC. TYPE: Additional Information
DECISION/STATUS: SE
CONSULTING REV: Wolf Sapirstein, M.D.

RESPONSE TO DOYLE MEMO

The reviews for additional information basically in general have been limited to reviews only of the additional information received rather than on all issues, since all issues were reviewed at the time of the original review. The additional review in question is no exception. Answers to some of the issues referred in your memo is included in my original memo. However, for the purpose of clarification and completion all the relevant information has been included here.

Difference between the Subject Device and the Predicate Device: The Cook Coil Positioner

(b) (4)

(b) (4)

CLASS III SUMMARY: Attached to the inside cover.

POSTMARKET SURVEILLANCE: The device was initially in the list of devices subject to Postmarket Surveillance, but now it is exempted from Postmarket Surveillance. -



REVIEWER: J. Roy DIVISION/BRANCH: DCRND / PRDB

TRADE NAME: Coil Positioner Set COMMON NAME: _____

PRODUCT TO WHICH COMPARED: ~~XXXXXX~~ Coil Embolization Coil
(510(k) NUMBER IF KNOWN) (K 90122)

YES	(NO)
-----	------

- 1. IS PRODUCT A DEVICE?

✓	
---	--

 - IF NO STOP
- 2. 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 - 
- 5. SAME TECHNOLOGICAL CHARACTERISTICS?

✓	
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 - IF YES GO TO 7
- 6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?

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 - IF YES GO TO 8
- 7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?

✓	
---	--

 - IF NO GO TO 10 
- IF YES STOP
- 8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?

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 - IF YES STOP - 
- 9. ACCEPTED SCIENTIFIC METHODS EXIST?

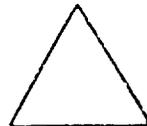
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 - IF NO STOP - 
- 10. PERFORMANCE DATA AVAILABLE?

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 - IF NO REQUEST DATA
- 11. DATA DEMONSTRATE EQUIVALENCE?

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 **NOTE:** IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

Handwritten initials/signature

NARRATIVE DEVICE DESCRIPTION

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. The following should be considered when preparing the summary of 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.

SUMMARY: _____



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



Memo Record

From: Chief, Prosthetic Devices Branch, HFZ-450
To: Joydeb Roy, Ph.D.
Date: August 10, 1994
Subject: K940189

=====

Your review memo dated August 9 is incomplete.

- Your memo needs to specify the exact differences between this device and the predicate device. Also, for each difference you should summarize and explain how the data demonstrates that the device is substantially equivalent to the predicate device.
- You must also fill out another review form which explains the logic path for your decision.
- The review form which is included in the original review indicates that clinical data must be provided to determine equivalence, yet no clinical data has been provided. Your review must explain this contradiction.
- You must also attach a copy of the class III summary to the inside cover of the file jacket which the company has written.
- You checked the box on the review form to indicate that this device type is subject to postmarket surveillance studies. Please contact Anita Rayner or one of her staff to determine if this is correct. Also, determine if this device is subject to tracking. If it is subject to postmarket surveillance studies and/or tracking a decision letter with the boilerplate paragraphs for these issues must be prepared.

If you have any questions concerning these instructions, please let me know.


A. Doyle Gantt

DIVISION OF CARDIOVASCULAR, RESPIRATORY & NEUROLOGICAL DEVICES

PROSTHETIC DEVICES BRANCH

REVIEW MEMORANDUM FOR FILE

FROM: JOYDEB ROY, Ph.D., (HFZ-450) *JR*
TO: File
REVIEW DATE: August 9, 1994
DOCUMENT#: K940189/A
DEVICE: Coil Positioner Set
MANUFACTURER: Cook Incorporated
Distributor: Cook Incorporated
DOC. TYPE: Additional Information
DECISION/STATUS: SE
CONSULTING REV: Wolf Sapirstein, M.D.

ADDITIONAL REVIEW

The company has responded to our letter of April 12, 1994 for additional information. They have now provided additional information regarding the device operation (i.e., coil deployment and retrieval), device modification and have provided several diagrams for further clarification. They have also provided a detailed description of the animal results as well. The Coil Positioner Set seems to have worked well in animal studies for both coil deployment as well as for retrieval. The animal data show that the device is safe and effective for its intended use.

Based on the information submitted, the device is judged SE to the predicate device.

NOTE: Wolf Sapirstein, M.D. has provided a consulting review on the device recommending approval.

MEMORANDUM

To: A. Doyle Gantt, Chief, PRDB/DCRND
Subject: Cook Coil Positioner Set. K940189
From: Wolf Sapirstein, Chief Medical Officer, DCRND 
Date: July 7, 1994
=====

I have reviewed the sponsors response to the FDA's request for additional information regarding the above 510(k) notification of April 12, 1994.

This response of May 19, 1994, provides details regarding the device mechanism and information concerning deployment in animal experiments. The information satisfactorily addresses questions raised in my memorandum of March 18, 1994.

I would concur with clearance of the Cook Coil Positioner Set as substantially equivalent to the predicate Target Therapeutic Coil Delivery System



Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

May 24, 1994

COOK INCORPORATED
925 SOUTH CURRY PIKE
P.O. BOX 489
BLOOMINGTON, IN 47402
ATTN: APRIL LAVENDER

510(k) Number: K940189
Product: COIL POSITIONER
SET

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

COOK[®]
Cook Incorporated

May 19, 1994

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Dr.
Rockville, MD 20850

RE: 510(k) Premarket Notification
DEVICE: Coil Positioner Set
D.C.#: K940189

FDA/CDRH/OBE/DMC

20 MAY 94 10 40

RECEIVED

Dear Sir or Madam:

The attached amendment to the 510(k) Premarket Notification referenced above provides answers to the inquiries from your letter dated April 12, 1994.

Thank you for your consideration of these data.

If additional information should be required to complete this review, please do not hesitate to contact the undersigned at 800-346-2686.

Sincerely,

COOK INCORPORATED



April Lavender
Manager, Regulatory Affairs

Enclosure



510(k) Premarket Notification Amendment
K940189 Coil Positioner Set

Page 2

Question #1 Stated:

(b)(4)

RESPONSE:

(b)(4)

510(k) Premarket Notification Amendment
K940189 Coil Positioner Set

Question #1 continued...

(b)(4)

510(k) Premarket Notification Amendment
K940189 Coil Positioner Set

Page 4

Question #1 continued...

(b)(4)

510(k) Premarket Notification Amendment
K940189 Coil Positioner Set

Page 5

Question #2 Stated:

(b)(4)

510(k) Premarket Notification Amendment
K940189 Coil Positioner Set

Page 6

Question #2 continued...

(b)(4)

510(k) Premarket Notification Amendment
K940189 Coil Positioner Set

Question #2 continued

(b)(4)

510(k) Premarket Notification Amendment
K940189 Coil Positioner Set

Page 8

Question #2 continued...

(b)(4)

510(k) Premarket Notification Amendment
K940189 Coil Positioner Set

Page 9

Question #2 continued..

(b)(4)



A

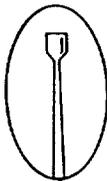
31

**COMPANY
CONFIDENTIAL**

FIGURE 1

CATHETER AND COIL SYSTEM ASSEMBLY





CONFIDENTIAL

FIGURE 2

SUB-ASSEMBLY OF FIGURE 1

GUIDE WIRE





FIGURE 3
SUB-ASSEMBLY OF FIGURE 1

COIL

Handwritten signature or initials.

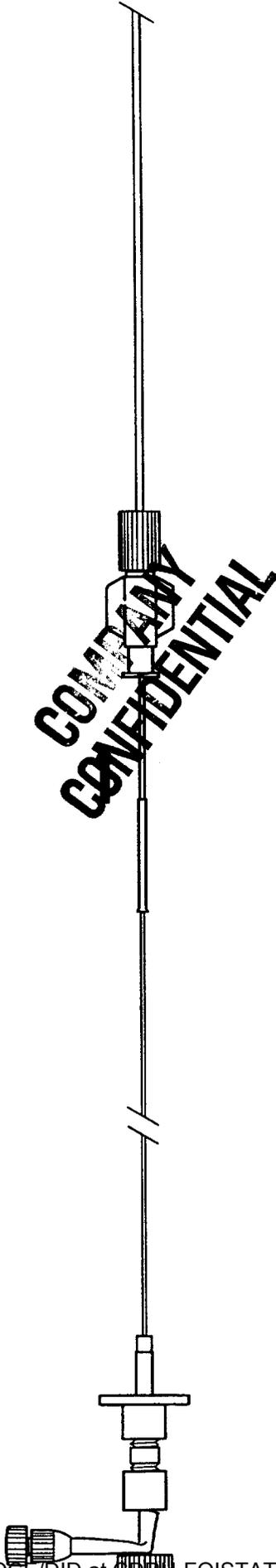


FIGURE 4

CATHETER AND COIL SYSTEM ASSEMBLY

**INSERTION OF COIL POSITIONER SET
INTO INTRAVASCULAR CATHETER**



FIGURE 5

COIL POSITIONER SET WITH COIL ATTACHED

Handwritten signature or initials.



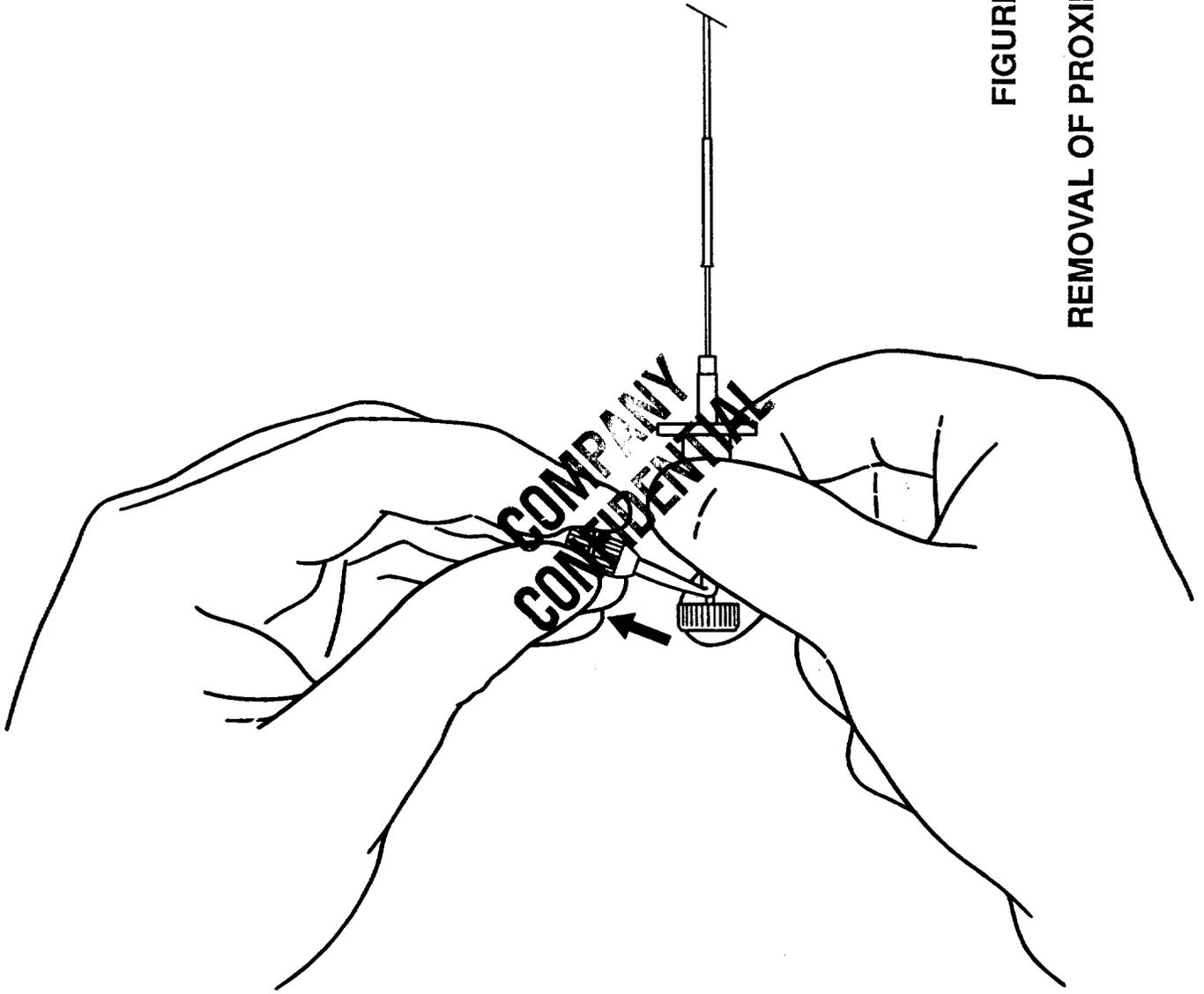
FIGURE 6

CLOSE-UP OF COIL AND ATTACHMENT

A handwritten signature or mark, possibly a stylized letter 'S' or a similar symbol, located in the bottom right corner of the page.

REMOVAL OF PROXIMAL PEEL-AWAY

FIGURE 7



Handwritten signature or initials.

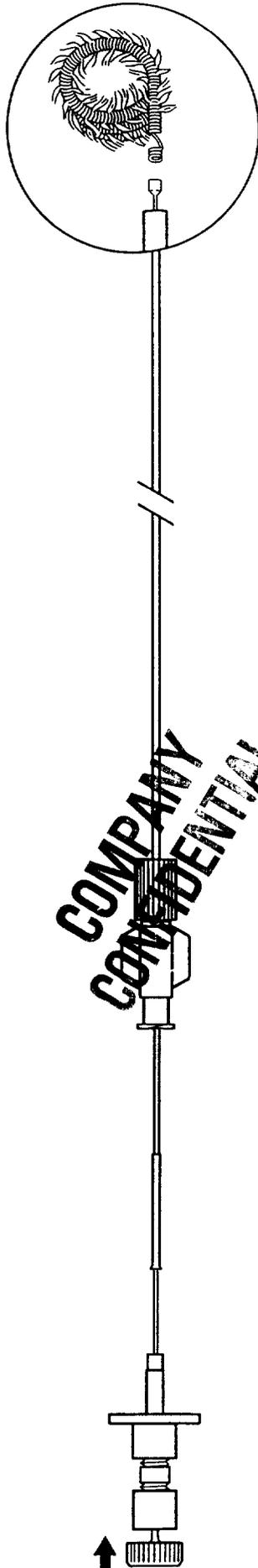
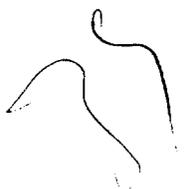


FIGURE 8
PUSH-BUTTON RELEASE FROM COIL POSITIONER SET



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

May 11, 1994

COOK INCORPORATED
925 SOUTH CURRY PIKE
P.O. BOX 489
BLOOMINGTON, IN 47402
ATTN: APRIL LAVENDER

510(k) Number: K940189
Product: COIL POSITIONER
SET

Extended Until: 12-JUN-94

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

COOK[®]

Cook Incorporated

May 6, 1994

Document Mail Center (HFZ-401)
Center for Devices and
Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

FDA/CDRH/OCE/DID

9 MAY 94 10 54

RECEIVED

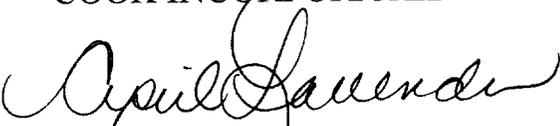
RE: K940189
Coil Positioner Set
Dated: January 12, 1994
Received: January 13, 1994

Dear Sir or Madam:

We have received your request for additional information concerning the above referenced premarket notification. We are collecting the necessary information to supply answers to your inquiries. In order to keep our file active, we would like permission for a 30-day extension on this submission review period.

Thank you for your assistance.

Sincerely,
COOK INCORPORATED


April Lavender

Manager, Regulatory Affairs





APR 12 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Ms. April Lavender
Manager, Regulatory Affairs
Cook Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, Indiana 47402

Re: K940189
Coil Positioner Set
Dated: January 12, 1994
Received: January 13, 1994

Dear Ms. Lavender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. We believe additional information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendment device with regard to its safety and effectiveness. In order for us to complete the review of your submission, we require the following additional information:

(b)(4)

Page 2 - Ms. April Lavender

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have questions concerning the contents of this letter, please contact Joydeb Roy, Ph.D., at (301) 594-2723. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or (301) 443-6597.

Sincerely yours,

Kenneth H. Palmer, Ph.D.

for Thomas J. Callahan, Ph.D.,
Acting Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER K940189 PANEL CV DIVISION DCRND BRANCH

TRADE NAME COIL POSITIONER SET

COMMON NAME COIL POSITIONER SET

PRODUCT CODE _____

APPLICANT COOK INCORPORATED

SHORT NAME COOK

CONTACT APRIL LAVENDER

DIVISION _____

ADDRESS 925 SOUTH CURRY PIKE

P.O. BOX 489

BLOOMINGTON, IN 47402

PHONE NO. (812) 339-2235

FAX NO. (812) 339-5369

MANUFACTURER COOK INCORPORATED

REGISTRATION NO. _____

DATE ON SUBMISSION 12-JAN-94

DATE DUE TO 510(K) STAFF 29-MAR-94

DATE RECEIVED IN ODE 13-JAN-94

DATE DECISION DUE 13-APR-94

OPr- DECISION _____

DECISION DATE _____

CORRESPONDENCE SENT DUE BACK

C001

12-APR-94

12-MAY-94

HOLD LETTER

PROPOSED USE _____

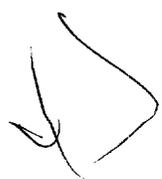
PROPOSED S.A.L. _____

PROPOSED STERILIZATION METHOD _____

IS THERE INFORMATION IN SUBMISSION WHICH SUPPORTS STERILIZATION METHOD? Y/N _

DATE FORWARDED TO POS FOR STERILITY INSPECTION PROGRAM __-__-__

REVIEWER INITIALS _____ PHONE () __-__



APR 12 1994

Ms. April Lavender
Manager, Regulatory Affairs
Cook Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, Indiana 47402

Re: K940189
Coil Positioner Set
Dated: January 12, 1994
Received: January 13, 1994

Dear Ms. Lavender:

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(b)(4)

Page 2 - Ms. April Lavender

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If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have questions concerning the contents of this letter, please contact Joydeb Roy, Ph.D., at (301) 594-2723. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or (301) 443-6597.

Sincerely yours,

Thomas J. Callahan, Ph.D.,
 Acting Director
 Division of Cardiovascular, Respiratory
 and Neurological Devices
 Office of Device Evaluation
 Center for Devices and
 Radiological Health

cc: HFZ-401
 HFZ-402
 HFZ-450

Prepared by: JROY:swf:4/6/94

FILE
 COPY

HFZ-450

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
JR	JR	4/12						
450	ITAMU	4/12						
450	Palmer	4/12/94						



Memorandum

Date _____

From REVIEWER(S) - NAME(S) JRM

Subject 510(k) NOTIFICATION K940189

To THE RECORD

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

- _____ (A) Is substantially equivalent to marketed devices.
- _____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- _____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes No

This 510(k) contains: (check appropriate box(es))

- A 510(k) summary of safety and effectiveness, or
- A 510(k) statement that safety and effectiveness information will be made available
- The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

Predicate Product Code w/panel and class:

- _____ No Confidentiality
- _____ Confidentiality for 90 days
- _____ Continued Confidentiality exceeding 90 days

Additional Product Code(s) w/Panel (optional):

REVIEW: _____

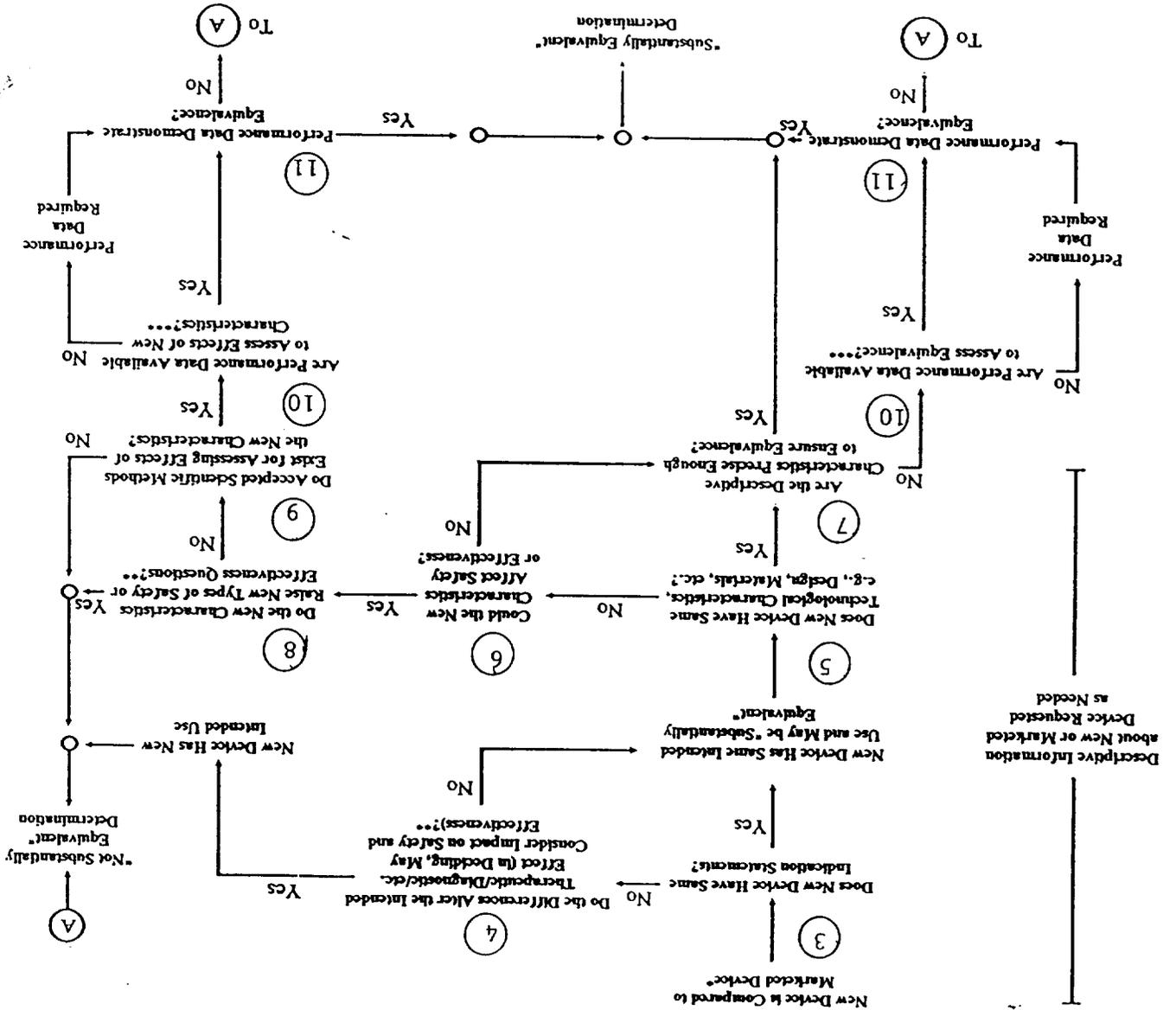
(BRANCH CHIEF) BRANCH CODE (DATE)

FINAL REVIEW: _____

(DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS
 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8799

**510(k) "SUBSTANTIAL EQUIVALENCE"
DECISION-MAKING PROCESS (DETAILED)**



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear. This decision is normally based on descriptive information alone, but limited testing information is sometimes required. ... Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DIVISION OF CARDIOVASCULAR, RESPIRATORY & NEUROLOGICAL DEVICES
PROSTHETIC DEVICES BRANCH

REVIEW MEMORANDUM FOR FILE

FROM: JOYDEB ROY, Ph.D., (HFZ-450) *JR*
TO: File
REVIEW DATE: March 21, 1994
DOCUMENT#: K940189
DEVICE: Coil Positioner Set
MANUFACTURER: Cook Incorporated
Distributor: Cook Incorporated
DOC. TYPE: Original
DECISION/STATUS: Additional Information
CONSULTING REV: Wolf Sapirstein, M.D.

ORIGINAL REVIEW

The device Coil Positioner Set is a combined catheter-guidewire-coil device for introduction of coils for vascular (arterial and venous) embolization purposes. The three device components are: (1) angiography vascular catheter, (2) embolization coils, and (3) guide wire. The components are marketed separately by the company -The embolization coils (Cook Incorporated Embolization Coils Order#MWCE-X-X-X Preamendment & D.C.#K901337), Catheter/guide wire set (Cook Incorporated Embolization Set, Order #GAO-1 Pre-Amendment). The device is claimed substantially equivalent to Target Therapeutics Embolization Coils and delivery system (Order #332xxx-#522xxx, D.C.#914786). Basically the company is claiming equivalency to one of Cook Incorporated preamendment device (Gianturco Coils) and also the Target Therapeutics device.

(b) (4)

Records Processed under FOIA Request 2015-6320; Released by CDRH on 10/07/2015.
As required by the Safe Medical Device Act (SMDA) of 1990, a "510 (k) Summary" of safety and effectiveness information has been provided. A bibliographic listing of embolization related papers and a list of some common complications inherent in the use of the coil embolization technique(s) has also been provided. The list contains several informative articles.

Appendix D provides biocompatibility data for materials used in the device. The material components remain unchanged from the marketed device(s). Appendix E provides a description of the invitro-testing done to assess the effectiveness of the Coil Positioning Set. A total of ten embolization coils and ten delivery catheters were deployed through a 0.3inch diameter clear teflon tubing. The tests were successful in deploying the coils. There were no failures.

(b)(4)

The device is claimed equivalent to the Embolization Coils and Delivery System manufactured by Target Therapeutics as well as Cook Incorporated Gianturco Coil system. Equivalency comparison is provided in Attachment H. The device will be supplied sterile and preassembled. The device will be delivered using Seldinger technique.

Consulting Review: I have requested Wolf Sapirstein, M.D. for a review of the file from the clinical perspective. He has provided a memo for the file. He is particularly concerned with the inadequacy of animal data since the modifications made in the device components are substantial.

I also talked to Lev Keely regarding the indications for use of this device and whether there is a need to restrict the indication for use. Presently, the device is indicated for arterial and venous embolization (See Attachment H). The device is indicated "in any patient with a medical need for a percutaneous transcatheter vascular occlusion procedure". Lev said he sees no reason to restrict the indication for use, as the indication is identical to the predicate device. In general, the embolization devices are used for arterio-ventricular malformations (AVMs) and fistulas. Indication for use statement in the submission does not suggest any neurological use for the device.

The issues for consideration are as follows:

(b)(4)

(b)(4)

RECOMMENDATION

A letter to be drafted seeking additional information on the issues raised in the review(s).



MEMORANDUM

To: Joydeb Roy, Engineer.
Through: Doyle Gantt, Chief, PRDB
From: Wolf Sapirstein, Chief Medical Officer
Subject: Coil Positioner Set
K 940189
Date: March 18, 1994

(b)(4)



REVIEWER: Jordan King DIVISION/BRANCH: - - RND / MLD15

TRADE NAME: Record Processed under FOIA Request 2015-6320; Released by CDRH on 10/07/2015
COMMON NAME: _____

PRODUCT TO WHICH COMPARED: K901337, K914786
(510(k) NUMBER IF KNOWN)

YES	NO
-----	----

- 1. IS PRODUCT A DEVICE?

✓	
---	--

 - IF NO STOP
- 2. 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 - 
- 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 - 
- 8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?

	✓
--	---

 - IF YES STOP - 
- 9. ACCEPTED SCIENTIFIC METHODS EXIST?

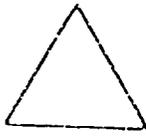
✓	
---	--

 - IF NO STOP - 
- 10. PERFORMANCE DATA AVAILABLE?

	✓
--	---

 - IF NO REQUEST DATA
- 11. DATA DEMONSTRATE EQUIVALENCE?

--	--



NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

Handwritten signature/initials

1. INTENDED USE: Embolization device - artificial / brain
Records Processed under FOIA Request 2015-6320; Released by CDRH on 10/07/2015
Vascular 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. The following should be considered when preparing the summary of 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.

SUMMARY

(b)(4)

1. EXPLAIN WHY NOT A DEVICE:

Records Processed under FOIA Request 2015-6320; Released by CDRH on 10/07/2015

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:

(b)(4)

(b)(4)

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:

The modification introduced in the design may have altered the safety and performance of the 3 components in the set.

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: clinical data, or animal data to support the claim of equivalency

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT: _____

ATTACH ADDITIONAL SUPPORTING INFORMATION



Premarket Notification (510(k)) Checklist for Acceptance Decision

K 940189 Date DMC Received Jan 13, 94

Device Trade Name: NOT available
Common Name: Core Positioner set
Reason for 510(k): New core release system

Division/Branch: DCRNP/PRPB

Administrative Reviewer Signature: _____ Date _____

Supervisory Signature: CP Gut Date 2/16/94

Did the firm request expedited review No

Did we grant expedited review No

accepted refuse to accept

Yes Present Omission Justified
 No Inadequate Omitted

I. Critical Elements:		
A. Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Is the device exempt from 510(k) by regulation or policy?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C. Is device subject to review by CDRH?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. (i) Are you aware that this device has been the subject of a previous NSE decision? (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/>	<input type="checkbox"/>

N/A

Yes Present Omission Justified
 No Inadequate Omitted

<p>F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:</p>								
<p>1. Device trade or proprietary name</p>								
<p>2. Device common or usual name or classification name</p>								
<p>3. Establishment registration number (only applies if establishment is registered)</p>								
<p>4. Class into which the device is classified under (21 CFR Parts 862 to 892)</p>								
<p>5. Classification Panel</p>								
<p>6. Action taken to comply with Section 514 of the Act</p>								
<p>7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)</p>								

Yes Present Omission Justified
 No Inadequate Omitted

	Yes Present Omission Justified	No Inadequate Omitted
8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9. For class III devices only, a class III certification and a class III summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10. Photographs of the device	<input checked="" type="checkbox"/>	<input type="checkbox"/>
11. Engineering drawings for the device with dimensions and tolerances	<input checked="" type="checkbox"/>	<input type="checkbox"/>
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device	<input checked="" type="checkbox"/>	<input type="checkbox"/>
13. Statement of similarities and/or differences with marketed device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14. Data to show consequences and effects of a modified device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
II. Additional Information that is necessary under 21 CFR 807.87(h):	<input checked="" type="checkbox"/>	<input type="checkbox"/>
A. Submitter's name and address	<input checked="" type="checkbox"/>	<input type="checkbox"/>



Yes Present Omission Justified
 No Inadequate Omitted

B. Contact person, telephone number and fax number	<input checked="" type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant if applicable	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. Table of Contents with pagination	<input checked="" type="checkbox"/>	<input type="checkbox"/>
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
III. Additional Information that may be necessary under 21 CFR 807.87(h):		
A. Comparison table of the new device to the marketed device(s)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Action taken to comply with voluntary standards	<input checked="" type="checkbox"/>	<input type="checkbox"/>
C. Performance data		
marketed device		
bench testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
animal testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
clinical data	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Yes Present Omission Justified No Inadequate Omitted

	Yes Present Omission Justified	No Inadequate Omitted
new device		
bench testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
animal testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
clinical data	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. Sterilization information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
E. Software information	<input type="checkbox"/>	<input type="checkbox"/>
F. Hardware information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
G. If this 510(k) is for a kit, has the kit certification statement been provided?	<input type="checkbox"/>	<input type="checkbox"/>
H. Is this device subject to issues that have been addressed in specific guidance document(s)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, continue review with checklist from any appropriate guidance documents.		
If no, is 510(k) sufficiently complete to allow substantive review?	<input checked="" type="checkbox"/>	

N/A

N/A



Yes
Present
Omission Justified

No
Inadequate
Omitted

I. Other (specify)	N/A	<input type="checkbox"/>	<input type="checkbox"/>
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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFE-401)
1390 Piccard Drive
Rockville, Maryland 20850

February 02, 1994

COOK INCORPORATED
925 SOUTH CURRY PIKE
P.O. BOX 489
BLOOMINGTON, IN 47402
ATTN: APRIL LAVENDER

510(k) Number: K940189
Received: 13-JAN-94
Product: COIL POSITIONER
SET

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.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- o Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
510(k) Status Coordinator
Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, Maryland 20857 USA
Because of staff limitations, we cannot answer telephone status requests.
- o 510(k) status requests should include:
(1) submitter's name and mailing address;
(2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

- (3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- o Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
 - (1) the branch to which the 510(k) has been assigned;
 - (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
 - (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. **Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.**

Additionally, the new legislation also requires any person asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

fax
 mail

A. Sponsor Information:

- 1. Name of 510(k) sponsor: _____
- 2. Sponsor's mailing address: _____

B. Requester information:

- 1. Request name: _____
- 2. Requester affiliation with sponsor: _____
- 3. Requester mailing address: _____

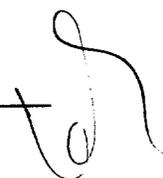
- 4. Request fax number (if applicable): _____
- 5. Requester telephone number: _____

C. 510(k) information:

- 1. Product name: _____
- 2. 510(k) number: _____
- 3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____

Name of contact person identified on firm's 510(k) submission: _____

.....
I certify that the above information is accurate and truthful to the best of my knowledge.

Requester signature 

(Rev:2)

510 (K) PREMARKET NOTIFICATION

Submitted by:

COOK INCORPORATED

925 South Curry Pike

P.O. Box 489

Bloomington, IN 47402

Phone: 1-800-346-2686

K940189

COOK®

Cook Incorporated

January 12, 1994

U.S. Food and Drug Administration
Office of Device Evaluation
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

RECEIVED
13 JAN 94 12 12
FDA/CDRH/OCE/DNC

RE: 510(k) PREMARKET NOTIFICATION
DEVICE: COIL POSITIONER SET

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, COOK INCORPORATED proposes to introduce into interstate commerce for commercial distribution a modified device intended for human use and hereby reports to the Food and Drug Administration as required by law. This premarket notification report is being submitted at least ninety (90) days prior to the date upon which COOK INCORPORATED proposes to begin the introduction of the device described herein.

The device, subject of this submission, will be identified as a Coil Positioner Set. COOK INCORPORATED currently markets vascular catheter(s), embolization coil(s) and wire guide(s). The Coil Positioner Set will contain these three components, i.e., a catheter, a wire guide and a coil. The purpose of this premarket notification is to describe device modifications which will be required to market these items in a set system. The spring of the coil body will be modified by adding a space between the coil windings. The wire guide will be modified at its distal tip with a tip weld. The tip weld will interconnect with the coil at its gap. A push-button release at the proximal end of the catheter will advance the coil at the time of desired coil deployment. Figures 1 through 4 have been provided in Appendix A to depict the modification(s) described above.

**Premarket Notification
Coil Positioner Set**

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A "510(k) Summary" of safety and effectiveness information pertinent to the substantial equivalence of this device has been provided both in Appendix B and in a separate attachment with this submission. This attachment is identified as a "510(k) Summary" and includes a certification statement as required by the Safe Medical Device Act (SMDA) of 1990.

Information contained in this premarket notification is deemed confidential and proprietary and we request that FDA maintain its confidentiality. COOK INCORPORATED has taken all reasonable and prudent precautions to protect the confidentiality of this information. Neither the information in this premarket notification nor its existence have been disclosed to anyone except employees of its establishment. Please do not make this information available through the Freedom of Information Act except as is required by law.

COOK INCORPORATED appreciates your consideration of these data. If additional information should be required regarding this submission, please do not hesitate to contact me at 800-346-2686.

Sincerely,

COOK INCORPORATED



April Lavender
Manager, Regulatory
Affairs

Enclosures



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Appendix H...Literature on Predicate Substantially Equivalent Devices

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1.0 DEVICE NAME

Classification Name: Embolization Device
Common/Usual Name: Coil Positioner Set
Trade Name: Not Available

2.0 DEVICE SPONSOR

Sponsor Name: COOK INCORPORATED
Sponsor Address: 925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Establishment
Registration Number: 1820334

Official Correspondent
and Address: April Lavender
Manager, Regulatory Affairs
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
PH: 812-339-2235 or
800-346-2686

3.0 CLASSIFICATION Class III

4.0 DESCRIPTION OF DEVICE

4.1 Intended Use

The Coil Positioner Set is used for arterial and venous embolization procedures. The device is supplied sterile in peel-open packages. It is intended for one-time use.

**Premarket Notification
Coil Positioner Set**

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4.2 Physical Composition

The device, subject of this submission, will be comprised of a pre-Amendment catheter, a cardiovascular wire guide (found substantially equivalent under Document Control No. K920891 in December of 1992), and a modified COOK embolization coil. These components can be further described as:

- A straight 3.0 French TFE catheter measuring 130 cm in overall length with a plastic push-button proximal fitting. 2-33
- A straight 0.018-inch diameter Roadrunner™ wire guide measuring 180 cm in overall length with a distal tip weld. 5-57
- An appropriate diameter embolization coil.
Reference pre-Amendment registration number A176789 for the stainless steel coils and Document Control No. K901337 for the platinum coils found substantially equivalent in December of 1990.
Please incorporate this premarket notification file by reference.

COOK INCORPORATED is requesting permission to make the described modifications and market these components as a set system. While the indications for use of the device will be identical to the current, legally marketed, indications as described for the embolization coils we now have in commercial distribution, the labeling for the proposed device will provide additional

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Coil Positioner Set**

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directions describing the method of operation of the set system. The method to use the device is described in more detail below.

4.3 Method of Operation

The embolization coil component of the device will be supplied in a coil holder, as are the currently marketed coils. The coil and coil holder will be interconnected at the distal tip of an 0.018-inch RoadrunnerTM wire guide. To use the device, the physician will insert the distal tip of the Coil Positioner Set into the proximal fitting of a standard angiographic catheter of choice. Using fluoroscopy, the Coil Positioner Set catheter will be advanced through the angiographic catheter. With this forward advancement of the assembly, the coil will be positioned for deployment in the vessel. When the coil is at the correct position, the physician depresses the release button on the coil positioner catheter to release the coil from the wire. This method of operation offers the physician selective control of the coil during its deployment. See Figures 1 through 4 in Appendix A for visual representations of this assembly.

4.4 Specifications

For confidential specifications and a list of raw materials for this device, refer to Appendix C. Photographs of the assembly have also been provided in Appendix C.

5.0 PERFORMANCE STANDARDS

No performance standards have been established under Section 514 of the Federal Food, Drug and Cosmetic Act for any devices comparable to the device, subject of this submission.

5.1 Biocompatibility Testing

The raw materials for the component assemblies for this device have been verified to be non-toxic, biocompatible materials suitable for human use. A chart which is supplied in Appendix D lists the testing which has been performed to validate these materials. Much of this data has been previously submitted to the Agency in various premarket notification and premarket approval applications. These tests assure that there are no new questions of biocompatibility for the device and that the device, subject of this submission, is comprised of materials which are nontoxic and suitable for use in a medical device.

5.2 Quality, Reliability and Functionality Testing

This product and its components will be subjected to rigorous quality testing as part of COOK INCORPORATED's Good Manufacturing Practices. Standard quality control methods employed for this device will include incoming, in-process quality control as well as a final inspection on each device at a 100% inspection level.

5.3 Design Validation Studies

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6.0 LABELING

Proposed labeling for this device is attached as Appendix G.

7.0 STATEMENT OF SUBSTANTIAL EQUIVALENCE

7.1 Background

Since the 1960's, transcatheter arterial embolization has been reported for the treatment and management of tumors, hemorrhage, and vascular malformations (aneurysms, arteriovenous fistulas, angiomas). Embolization materials have included

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autologous tissue and clot, thrombin mixtures, Gelfoam, wool, cotton, metallic and plastic spheres, tantalum powder, silicone preparations, instantly setting polymers such as isobutyl 2-cyanoacrylate, radioactive particles, intravascular balloons, Ivalon plugs, and metal springs or coils. Embolization procedures have been performed prophylactically, as an adjunct to surgical treatment, or as an alternative to surgical treatment in the poor-risk patient.

The device, subject of this submission, is equivalent to the COOK pre-Amendment coil and the COOK pre-Amendment arterial embolization set. Equivalence can be demonstrated with regard to design requirements, configuration, raw materials, technology, processing and intended use.

7.2 Similarities to Predicate Devices

7.2.1 Indications

As reported previously, the indications for use of the pre-Amendment MWCE coils and the Coil Positioner Set will be identical.

Not only is the Coil Positioner Set equivalent as concerns the coil component(s), it is also substantially equivalent to a pre-Amendment set that COOK INCORPORATED marketed in the mid-1970's called the Gianturco-Wallace-Anderson Arterial Embolization Set (GAO-1). The GAO device was comprised of an occluding spring embolus which was supplied in a TFE cartridge. The set



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consisted of a 7.0 French catheter with a matched pusher, a stainless steel spring embolus introducer and 10 emboli. The procedure to deploy the device was very similar to the coil positioner except that with the GAO set, the physician loaded the coil onto the spring embolus introducer and advanced it through the catheter with the spring embolus pusher device. The Coil Positioner Set will be supplied with a coil pre-loaded in its delivery system. Further equivalence between these devices can be demonstrated by the fact that the raw materials which were used to fabricate the GAO set are also used to fabricate the Coil Positioner Set. In addition, both of these devices include the same indications for use, i.e., arterial and/or venous embolization procedures. Equivalence can also be documented in describing the method of use of the devices. As with the GAO, the Coil Positioner Set includes a catheter, wire pusher and coil. Percutaneous entry into the vessel using the Seldinger technique is common between the two as is the use of catheter delivery for deployment. The major difference in the method of deployment for the Coil Positioner Set is that the new device includes a push-button release handle on the delivery catheter. A diagram of the pre-Amendment GAO set is provided in Appendix H of this document, which illustrates the components which were used with this pre-Amendment system.



**Premarket Notification
Coil Positioner Set**

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Another substantially equivalent device to the Coil Positioner Set is Target Therapeutic's Coil Delivery System, which was found substantially equivalent under FDA's Document Control No. K891688 in September of 1989.

Like the Coil Positioner Set, the Target Therapeutic Catheter System is also comprised of a small profile TFE catheter and a coil pusher fabricated with stainless steel and TFE. Its indications for use are the same as the device subject of this submission. It is technologically similar in its configuration, size range and raw materials which comprise the device.

Like the Target device, the Coil Positioner Set, subject of this submission, will be packaged and sterilized using validated materials and processes which are comparable with other currently legally marketed COOK products. Further, these packaging materials are identical to the material currently used for coils and catheters when supplied individually.

7.2.2 Method of Operation

The method of using the COOK pre-Amendment coils, the COOK pre-Amendment GAO-1 set, the Target Therapeutic coil positioner and the COOK Coil Positioner Set are almost identical. With each of these devices, a low profile diameter catheter is used to pass the coil to its target destination *in-vivo*. This forward advancement of the coil occurs through the use of a "pusher" wire, which is used inside the lumen of the

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Coil Positioner Set**

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coil delivery catheter. Upon exiting the distal tip of the catheter, the coil detaches (or is mechanically released with the positioner set) from the catheter's lumen. All instrumentation used to deliver the coil is then removed from the vessel, leaving the coil in its deployed position in the vessel.

7.2.3 Technology

No new technology is required to produce the device subject of this submission. The technology which is employed by both COOK and Target Therapeutic in the fabrication of the pre-Amendment coils, the Target coil positioner and this device will be similar. In addition, product requirements between the pre-Amendment and predicate devices to this device are equivalent, i.e., biocompatibility, dimensional, and functional reliability. Since the device is intended to perform the same intended function as its pre-Amendment and predicate counterparts, design requirements between these products are identical, and are therefore, unchanged from these pre-Amendment and predicate devices.

7.2.4 Materials/Specifications

Materials and specifications for the new device as compared to the pre-Amendment devices and the Target Therapeutic coil positioner device are equivalent. Table 1 in Appendix H provides a tabular presentation of equivalent characteristics amongst these devices.



**Premarket Notification
Coil Positioner Set**

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7.3 Dissimilarities to Predicate Devices

7.3.1 Method of Operation

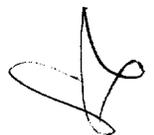
The method of operation for the Coil Positioner Set differs only slightly from the pre-Amendment devices and the Target Therapeutic device. This difference will be that the device, subject of this submission, will be provided as a set system with the coil, the coil delivery catheter and wire pusher interconnected until released by the operator.

7.4 Do any of the dissimilarities between the predicate devices and the Coil Positioner Set raise different questions of safety or effectiveness?

There are no new different unanswered questions of safety or effectiveness that are raised by the combination of these products into a set.

7.5 Potential Benefits of the Coil Positioner Set

The benefit of offering these components as a set are that the operator will have precise control over his/her ability to correctly position the coil at its target destination and will, in addition, enable the user to purchase one set as compared to keeping inventory of three individual components, i.e., catheter, guide and coil.



**Premarket Notification
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7.6 Conclusions

On the basis of the foregoing, and in consideration of COOK INCORPORATED's design validation studies, it appears that the Coil Positioner Set is substantially equivalent in its design requirements, technological features, method of operation, raw materials and intended use are sufficient to warrant permission for market release of this modified device.



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Coil Positioner Set**

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8.0 OTHER INFORMATION

8.1 Packaging

The Coil Positioner Set will be supplied sterile and is intended for one-time use. Each unit will be packaged in a [REDACTED] (b)(4) [REDACTED] paper pouch that will be sealed and sterilized in an Ethylene Oxide sterilization cycle. This peel-pouch packaging system has a long history of use in COOK INCORPORATED processing. Tests with this packaging system have verified that sterility of the device can be maintained indefinitely as long as the packaging is intact.

8.2 Sterilization

It is the intent of COOK INCORPORATED to comply with all requirements for marketing the Coil Positioner Set as a sterile product. The method of sterilization is Ethylene Oxide (12/88 mixture), with the sterility assurance level at a minimum of 10^{-6} . The method that will be used to validate the sterilization cycle will be the Combined Biological Indicator/Bioburden Method as stated in Section 4.4.5 of the ST27-1988 Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices (AAMI Standards). The maximum allowable levels of residual that will remain on the device after sterilization will not exceed the following:

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**Premarket Notification
Coil Positioner Set**

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Ethylene Oxide.....	25 ppm
Ethylene Chlorohydrin.....	25 ppm
Ethylene Glycol.....	250 ppm

9.0 SAFETY AND EFFECTIVENESS

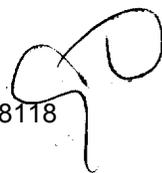
Information on safety and effectiveness has been supplied in Appendix B.

10.0 CONFIDENTIALITY

Information contained in this premarket notification is deemed confidential and proprietary and we request that FDA maintain its confidentiality. COOK INCORPORATED has taken all reasonable and prudent precautions to protect the confidentiality of this information. Neither the information in this premarket notification nor its existence have been disclosed to anyone except employees of its establishment. Please do not make this information available through the Freedom of Information Act except as is required by law.



A



**Premarket Notification
Coil Positioner Set**

Appendix A

Illustrations of Coil Positioner Set Assembly



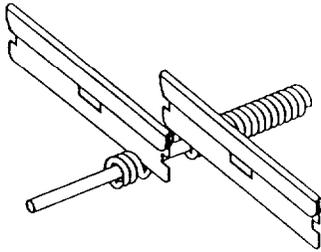


FIGURE 1

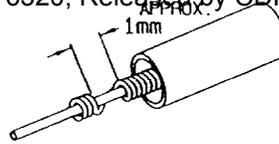


FIGURE 2

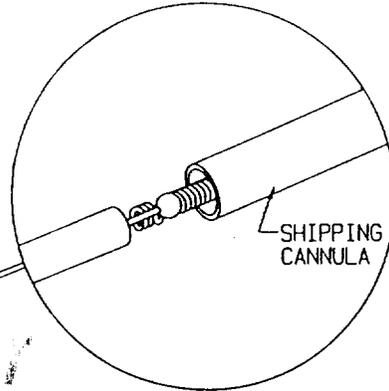
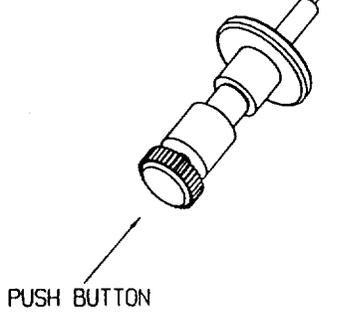


FIGURE 3

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PUSH BUTTON

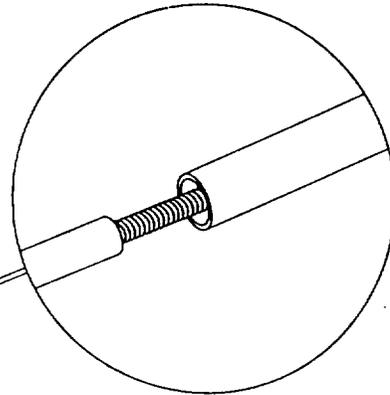


FIGURE 4



RELEASE BUTTON

	COOK INCORPORATED BOX 489 BLOOMINGTON, INDIANA 47402 © COPYRIGHT COOK INCORPORATED _____		DRAWN BY SD DATE 6-9-93 CHECKED BY
	TITLE POSITIONING SET FOR EMBOLIZATION COIL		SH. 1 OF 1 DRAWING NO. SK-6-9-93-SD
NO.	Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118		

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**Premarket Notification
Coil Positioner Set**

**Appendix B
510(K) Summary**

510-(K) PREMARKET NOTIFICATION

**SAFETY AND EFFECTIVENESS
INFORMATION AS REQUIRED
UNDER § 513 (i)(3)(A)**

Submitted by:

**COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Phone: 1-800-346-2686**

Premarket Notification
Coil Positioner Set

Certification

I certify that a reasonable search of information known or otherwise available to me has been conducted about the types and causes of safety and/or effectiveness problems that have been reported for arterial embolization devices. I further certify that I am aware of the types of problems to which arterial embolization devices are susceptible and that the following summary of the types and causes of safety and/or effectiveness problems about arterial embolization devices is reasonably complete and accurate to the best of my knowledge. From the search conducted under my direction, the following information summarizes substantial equivalence and safety and effectiveness information associated with arterial embolization devices and provides the literature citations upon which this summary is based.

Prepared By

Submitter's Name.....COOK INCORPORATED
Address.....925 S. Curry Pike, P.O. Box 489
.....Bloomington, Indiana 47402
Phone Number.....812-339-2235 or 800-346-2686
Contact Person.....April Lavender, Mgr. Regulatory Affairs
Signature.....*April Lavender*
Date of Summary.....January 12, 1994

Name of Device

Trade Name.....None Established
Common Usual Name....Coil Positioner Set
Classification Name..Arterial Embolization Device

Name of Predicate or Legally Marketed Comparison

<u>Name of Device</u>	<u>Manufactured By</u>
Embolization Coils and GAO Set	COOK INCORPORATED Bloomington, Indiana
Embolization Coils and Delivery System	Target Therapeutics San Jose, California

Describe the Device

Function

The device, subject of this submission, is intended to function in an identical manner to the pre-Amendment coils and the predicate coils to which it is compared to as shown above. The device, subject of this submission, is comprised of components which are already being legally marketed by COOK INCORPORATED. The purpose of this 510(k) notification is to describe a set system which will be supplied sterile and preassembled that will be used to deliver the coil to its desired vascular destination.

Basic Scientific Concept

The basic scientific concept of the component assembly, subject of this submission, relates to a modification in the components' design which will allow the coil to be deployed with a release mechanism controlled by the physician. This development in the COOK product family of occlusion devices is substantially equivalent to the Target Therapeutics selective vascular occlusion system(s). Like the Coil Positioner Set, these competitive devices are selectively deployed with catheter systems that are provided specifically for coil deployment.

Device Design

The device design was developed to accommodate the standard coil material and configuration, a modified wire guide and a low profile TFE delivery catheter with proximal push-button. The coil remains attached to the distal tip of



Premarket Notification
Coil Positioner Set

Page 3

the wire guide and remains housed in the TFE catheter until the desired time of deployment. At the time of desired coil deployment, the physician depresses the proximal handle to advance the coil out of the end of the catheter.

Physical properties of the device, subject of this submission, are identical to the legally marketed pre-Amendment and predicate devices mentioned above. The combination of these devices into a Coil Positioner Set does not significantly change any of their physical properties.

Indications for Use

This device is indicated in any patient with a medical need for a percutaneous transcatheter vascular occlusion procedure.

Summary of Safety/Effectiveness Problems

Since the 1960's, transcatheter arterial embolization has been reported for the treatment and management of tumors, hemorrhage, and vascular malformations (aneurysms, arteriovenous fistulas, angiomas). Embolization materials have included autologous tissue and clot, thrombin mixtures, Gelfoam, wool, cotton, metallic and plastic spheres, tantalum powder, silicone preparations, instantly setting polymers such as isobutyl 2-cyanoacrylate, radioactive particles, intravascular balloons, Ivalon plugs, and metal springs or coils. Embolization procedures have been performed prophylactically, as an adjunct to surgical treatment, or as an alternative to surgical treatment in the poor-risk patient. We have provided the following information to

Premarket Notification
Coil Positioner Set

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summarize the types and causes of reported safety and/or effectiveness problems with all types of embolization devices as well as adverse safety and effectiveness data, i.e., problems to which these types of predicate devices are susceptible and the potential causes of such problems.

This summary includes a review of 21 published articles dating from ~~1976~~ to 1993. The feasibility and efficacy for the use of the COOK Coil Positioner Set can be shown by the widespread history of coil use and successful clinical results associated with coil embolization devices. Please refer to the summary table and bibliography which follow.

Premarket Notification
Coil Positioner Set

SUMMARY TABLE
TYPES AND CAUSES OF SAFETY AND/OR EFFECTIVENESS PROBLEMS OF ARTERIAL EMBOLIZATION COILS

PROBLEM	CAUSE	COMMENT	REF.
Post-Emboic Syndrome (localized pain, fever, transient hypertension, leucocytosis, hematuria, nausea, vomiting, ileus)	<ul style="list-style-type: none"> Expected response due to vessel occlusion and tissue infarction 	<ul style="list-style-type: none"> Symptoms usually subside within 12 to 96 hours, are typically mild, and may be minimized using narcotics and antipyretics 	1-4,6,8,11,13,14,16,18,21
Inadvertent Embolization and/or Misplaced Coils	<ul style="list-style-type: none"> Use of inappropriate size coil Reflux during placement Passage through large AV shunts Displacement during subsequent surgery Extrusion of coil from catheter tip Use of inappropriate catheter Introduction under high-flow conditions Excessive vessel tortuosity 	<ul style="list-style-type: none"> Carefully select coil size for target vessel Use careful catheter technique and sequential embolization with intermittent filming Use customized introducing catheter Use appropriate amount of embolic material Conduct careful, continuous hemodynamic monitoring Use special care in high-flow conditions Achieve equilibrium between embolizing target area and avoiding ischemic necrosis of non-target areas 	1-13,16,17,19-21
Thromboembolism	<ul style="list-style-type: none"> Typical complication related to angiography procedure Retrograde propagation of thrombus from embolized artery Stripping of adherent thrombus from introducing catheter during catheter removal Vessel trauma 	<ul style="list-style-type: none"> Use systemic heparinization, if necessary Use careful catheter technique 	1-4,21
Renal Failure	<ul style="list-style-type: none"> May result from renal tumor infarction Possibly related to use of excess contrast agent 	<ul style="list-style-type: none"> Avoid use of excess contrast agent by performing diagnostic and therapeutic procedures on separate days Immediately analyze/monitor kidney function 	1-3,6
Large Renal Volume Loss	<ul style="list-style-type: none"> General vessel embolization (vs. specific) Multiple embolizations performed Incorrect proximal coil placement 	<ul style="list-style-type: none"> Conduct careful search for specific bleeding branch prior to embolization Avoid multiple embolizations, if possible Perform distal occlusion, if possible 	13,16
Prolonged Hypertension	<ul style="list-style-type: none"> Renal tissue ischemia may cause release of renal plasma renin 	<ul style="list-style-type: none"> Consider hematologic status of patient Immediately analyze function of other kidney for inadvertent embolization 	6
Post-Infarction Abscess	<ul style="list-style-type: none"> May result from infarcted tissue Immunosuppressed patient more susceptible 	<ul style="list-style-type: none"> Use careful sterile techniques and possible antibiotic coverage Monitor tissue response to embolism 	1-4,6

Premarket Notification
Coil Positioner Set

SUMMARY TABLE (CONTINUED)

PROBLEM	CAUSE	COMMENT	REF.
Aneurysm or Pseudo-Aneurysm formation	<ul style="list-style-type: none"> •May develop from collateral flow •Arterial puncture site susceptible 	<ul style="list-style-type: none"> •Consider collateral blood supply •Use low pressure delivery system •Use proximal and distal occlusion to prevent retrograde filling of a lesion 	6, 15, 18, 21
Incomplete Occlusion	<ul style="list-style-type: none"> •Coil lodges in catheter, preventing placement •Coil(s) placed too proximally •Development of collateral flow •Excessive vessel tortuosity 	<ul style="list-style-type: none"> •Consider collateral blood supply •Embolize distally to allow for supplemental embolization, if necessary 	7, 15, 18, 21
Hemorrhage	<ul style="list-style-type: none"> •Vessel or aneurysm wall perforation or rupture by guide wire, catheter or device 	<ul style="list-style-type: none"> •Use careful catheter technique •Conduct careful, continuous hemodynamic monitoring 	8, 19, 20
Intimal Dissection	<ul style="list-style-type: none"> •Excessive vessel tortuosity •Use of inappropriate catheter or guide wire 	<ul style="list-style-type: none"> •Use careful catheter technique with appropriate size coils 	16, 21
Congestive Heart Failure	<ul style="list-style-type: none"> •Overzealous administration of fluids, blood, and components 	<ul style="list-style-type: none"> •Conduct careful, continuous hemodynamic monitoring 	9
Dysphagia	<ul style="list-style-type: none"> •Embolization of distal esophageal arterial branches 	<ul style="list-style-type: none"> •Use careful catheter technique •Conduct careful, continuous hemodynamic monitoring 	18
Contrast Extravasation	<ul style="list-style-type: none"> •Not specified 	<ul style="list-style-type: none"> •Use careful catheter technique 	16
Massive Release of Humoral Substances	<ul style="list-style-type: none"> •"Theoretical" complication possibly related to infarction of endocrine tissues 	<ul style="list-style-type: none"> •Monitor tissue response to embolism 	4

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Coil Positioner Set

Page 8

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**Premarket Notification
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**Appendix C
Specifications and Photographs**

POS

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Coil Positioner Set

BILL OF MATERIAL AND SPECIFICATIONS

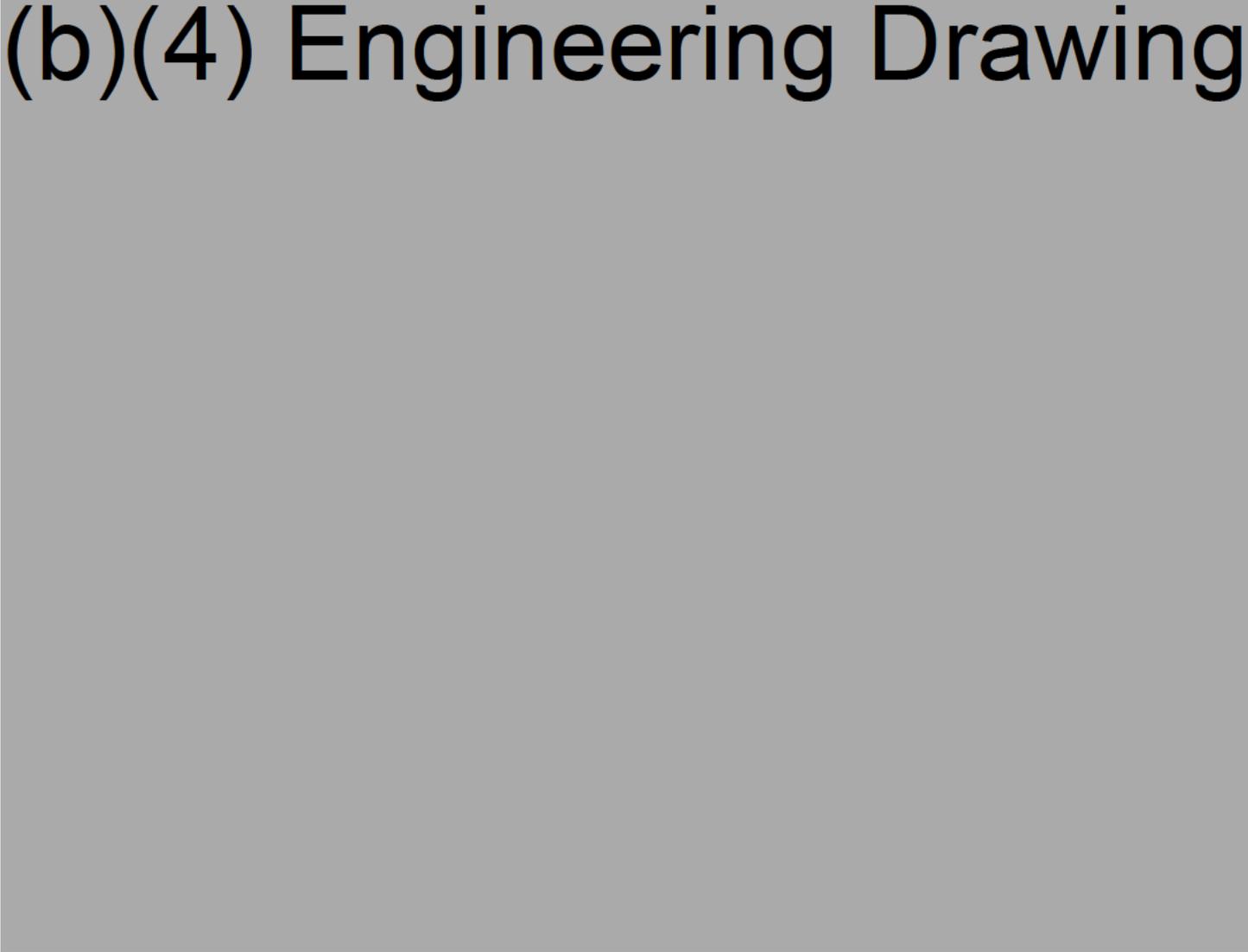
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Specification Number

- | | |
|--|-------------------------|
| a) 3.0 TFE Tubing | M.S.#121 |
| b) 5.0 TFE Tubing (Reinforcement sleeve) | M.S.#121 |
| c) 4.0 French Cap | Dwg.#1073-2 |
| d) Modified RSTF-18-180 with tip weld | M.I.#70 |
| e) Delrin Push-button Assembly with | Dwg.#SK9393SD |
| ▪ stainless steel spring | Dwg.#10186 |
| ▪ Loctite 401 | CPN#2128 |
| f) Modified MWCE coil with proximal end stretched as illustrated | Dwg.#SK6993SD
M.I.#1 |

M.S.=material specification
Dwg.=drawing
M.I.=manufacturing instruction
CPN#=COOK part no.

(b)(4) Engineering Drawing



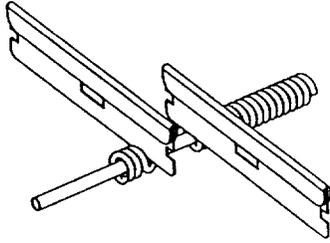


FIGURE 1

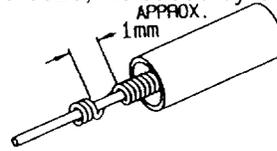


FIGURE 2

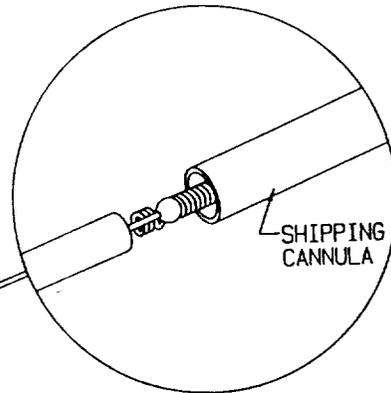
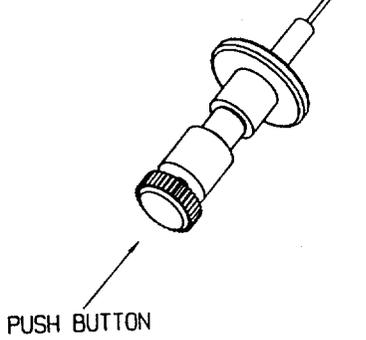


FIGURE 3

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PUSH BUTTON

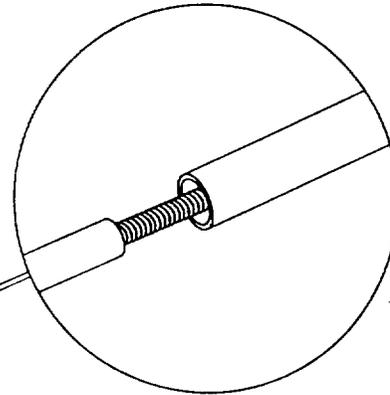
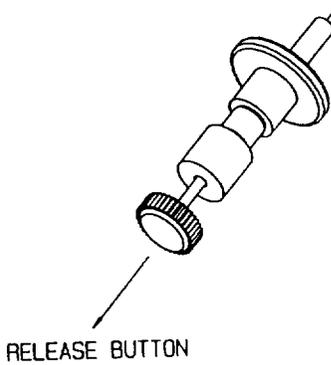


FIGURE 4



RELEASE BUTTON

<p>COOK INCORPORATED BOX 489 BLOOMINGTON, INDIANA 47402 © COPYRIGHT COOK INCORPORATED</p>		<p>DRAWN BY SD</p>
		<p>DATE 6-9-93</p>
<p>TITLE POSITIONING SET FOR EMBOLIZATION COIL</p>		<p>CHECKED BY</p>
		<p>SH. 1 OF 1</p>
<p>Questions? Contact FDA/CDRH/OCE/DIV-4 at CDRH.FO.I.STATUS@fda.hhs.gov or 301-796-8118</p>		<p>DRAWING NO. SK-6-9-93-SD</p>
<p>NO. REVISIONS</p>		

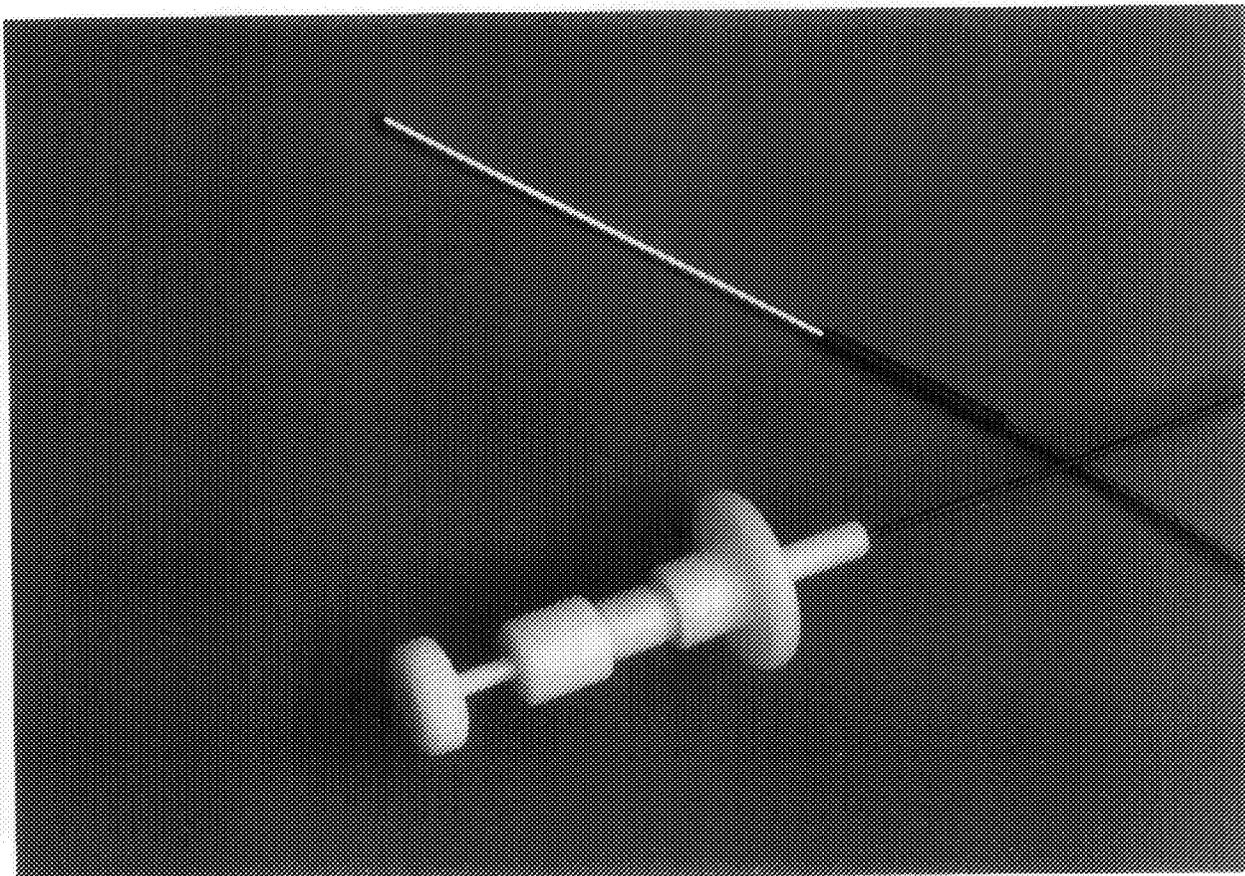
08

(b)(4) Engineering Drawing

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PHOTOGRAPH OF THE DEVICE



THIS PHOTO ILLUSTRATES BOTH THE PROXIMAL AND DISTAL ENDS OF THE COIL POSITIONER SET.

THE PROXIMAL END OF THE COIL POSITIONER SET IS EQUIPPED WITH A NYLON PUSH-BUTTON RELEASE HANDLE WHICH, WHEN DEPRESSED, ADVANCES THE COIL OUT OF THE TPE CATHETER.

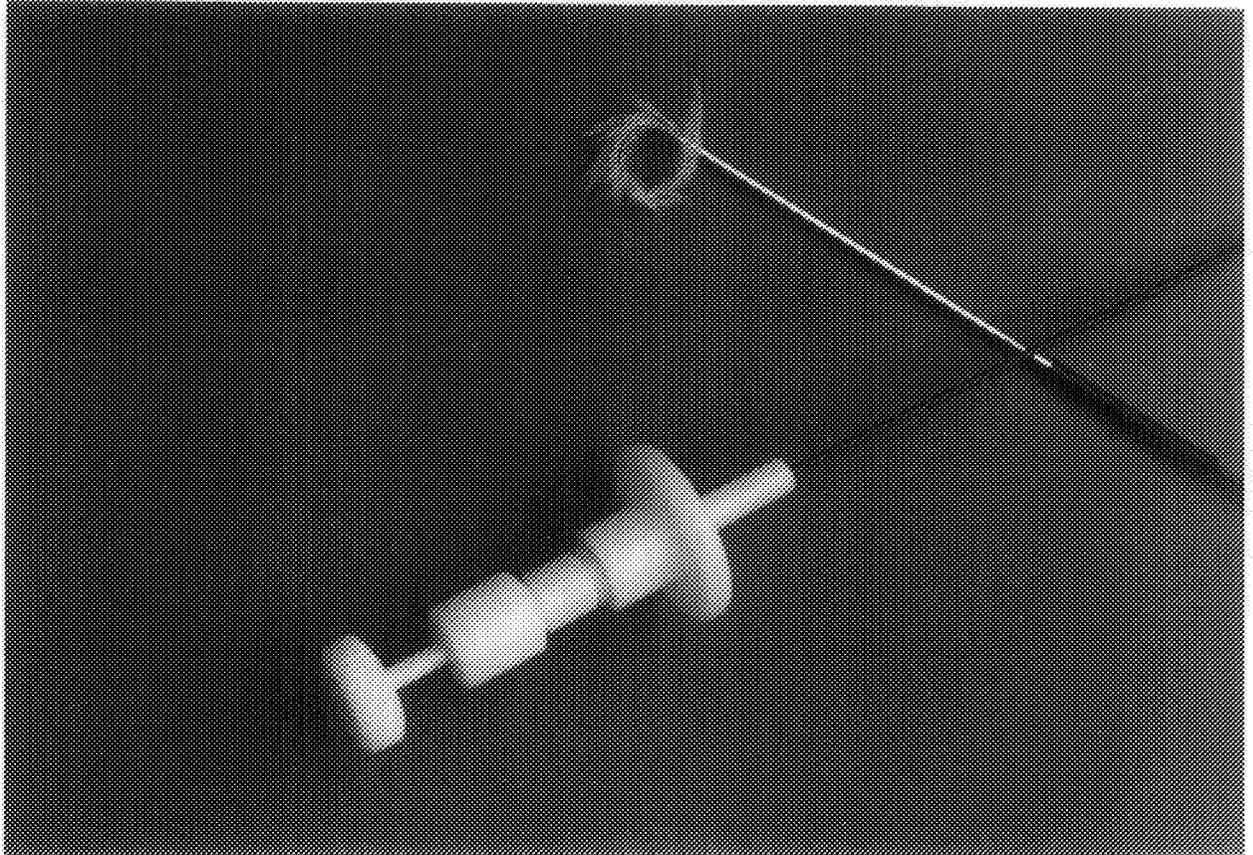
THE DISTAL END OF THE COIL POSITIONER SET AS SHOWN HERE INCLUDES THE STAINLESS STEEL COIL HOLDER. THE COIL HOLDER FUNCTIONS ONLY TO ALIGN THE COIL POSITIONER CATHETER ASSEMBLY THROUGH THE PROXIMAL FITTING OF AN ANGIOGRAPHIC CATHETER DURING INSERTION.

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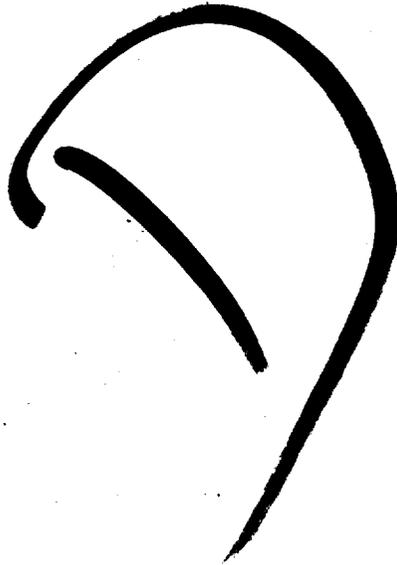
Premarket Notification
Coil Positioner Set

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PHOTOGRAPH OF THE DEVICE



THIS PHOTO ILLUSTRATES BOTH THE PROXIMAL AND DISTAL ENDS OF THE COIL POSITIONER SET. HOWEVER, THIS PHOTO EXHIBITS THE APPEARANCE OF THE SET WITH THE COIL EXTRUDED FROM THE END OF THE CATHETER.



Handwritten initials or signature

**Premarket Notification
Coil Positioner Set**

**Appendix D
Biocompatibility Test Data**



**Premarket Notification
Coil Positioner Set**

Biocompatibility Test Data
for TFE and Stainless Steel

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(b)(4) 3rd Party Testing

Records Processed Under FOIA Request 2015-0120 Released by CDRH on 11/07/2015

(b)(4) 3rd Party Testing

Records Processed Under FOIA Request 2015-0120 Released by CDRH on 11/07/2015

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Records Processed Under FOIA Request 2015-0120 Released by CDRH on 11/07/2015

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Records Processed Under FOIA Request 2015-0120 Released by CDRH on 11/07/2015

(b)(4) 3rd Party Sterilization Testing

Records Processed under FOIA Request 2015-0620, Released by CDRH on 10/07/2015

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Records Processed under FOIA Request 2015-0620, Released by CDRH on 10/07/2015

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Records Processed under FOIA Request 2015-0520; Released by CDRH on 10/07/2015

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**Premarket Notification
Coil Positioner Set**

**Biocompatibility Test Data for
Platinum MWCE Coils**

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(b)(4) 3rd Party Sterilization Testing

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Records Processed under FOIA Request 2015-0520; Released by CDRH on 10/07/2015

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(b)(4) 3rd Party Sterilization Testing

Records Processed under FOIA Request 2015-0620, Released by CDRH on 10/07/2015

(b)(4) 3rd Party Sterilization Testing

Records Processed under FOIA Request 2015-0620, Released by CDRH on 10/07/2015

(b)(4) 3rd Party Sterilization Testing

Records Processed under FOIA Request 2015-0520, Released by CDRH on 10/07/2015

(b)(4) 3rd Party Sterilization Testing

Records Processed under FOIA Request 2015-0620, Released by CDRH on 10/07/2015

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Records Processed Under FOIA Request 2015-0120 Released by CDRH on 11/07/2015

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Records Processed Under FOIA Request 2015-0120 Released by CDRH on 11/07/2015

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Handwritten initials or signature

**Premarket Notification
Coil Positioner Set**

**Appendix E
In-vitro Testing**

A handwritten signature or set of initials, possibly 'SP', located in the bottom right corner of the page.

(b)(4) Testing Methods and Results

Records Processed under FOIA Request 2015-6526, Released by CDRH on 10/07/2015

(b)(4) Testing Methods and Results

Records Processed under FOIA Request 2015-6526, Released by CDRH on 10/07/2015

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(b)(4) Testing Methods and Results

Records Processed under FOIA Request 2015-6526, Released by CDRH on 10/07/2015

A large, thick, black handwritten mark that resembles a stylized letter 'V' or the number '7'. It is oriented vertically and has a slightly irregular, hand-drawn appearance.A small, handwritten signature or set of initials in the bottom right corner of the page. The handwriting is cursive and appears to be 'ML'.

**Premarket Notification
Coil Positioner Set**

**Appendix F
Non-clinical Testing**

A handwritten signature or set of initials in black ink, located in the bottom right corner of the page. The signature is stylized and appears to consist of several overlapping loops and lines.

(b) (4)

G

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**Premarket Notification
Coil Positioner Set**

**Appendix G
Sample of Draft Labeling**

A handwritten signature in black ink, consisting of stylized, cursive letters, likely initials or a name, located in the bottom right corner of the page.

**Premarket Notification
Coil Positioner Set**

SAMPLE OF OUTER BAG LABEL

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

REORDER# ECPS-35-4-3
EMBOLIZATION COIL POSITIONER SET
CONSISTS OF: T3.0 FRENCH CATHETER
130 CM LONG
RSTF-18-180 CM WIRE GUIDE
4 CM LONG, 3MM DIA. COIL
LOT NO. TEST
DO NOT USE AFTER 03/96

CC6 788

A Cook Group Company
P.O. Box 489 Bloomington, IN 47402 USA



**Premarket Notification
Coil Positioner Set**

SUGGESTED INSTRUCTIONS FOR USE

Indications for Use

Used for arterial and venous embolization. Supplied sterile in peel-open packages. Intended for one-time use.

Contraindications

None known.

Warnings

This device is intended for use with its delivery components. Not recommended for use with polyurethane catheters or catheters with sideports.

Precautions

To minimize the possibility of a loose coil becoming dislodged and obstructing a normal arterial channel, the following recommendations should be considered:

- Spring coil should not be deployed too close to the inlet of the artery being embolized.
- Spring coil(s) may be intermeshed if required for correct positioning.
- Select appropriate size coil to wedge against the arterial wall.
- A minimal but sufficient arterial blood flow should remain to hold the coil in position until a solid clot insures permanent fixation.

Potential Adverse Reactions

Thromboembolism
Intimal Dissection
Renal Failure
Fever
Leucocytosis
Aneurysm

Pseudoaneurysm
Hemorrhage
Pain
Hypertension
Hematuria
Nausea



**Premarket Notification
Coil Positioner Set**

Directions for Use

This catheter assembly is supplied sterile intended for one-time use.

A DIAGRAM OF THE DEVICE COMPONENTS WILL APPEAR HERE

1. Position loading cartridge with catheter assembly into base of hub on an angiographic catheter with an 0.035-inch endhole.
2. Maintain the position of the loading cartridge in the hub of the catheter and advance the coil positioner catheter into the pre-positioned angiographic catheter.
3. Using fluoroscopy, advance the coil positioner catheter until it reaches the distal tip of the pre-positioned angiographic catheter.
4. After confirming proper position of the angiographic catheter, advance coil into the desired location.
NOTE: The coil will remain attached to the coil positioner system during this maneuver and can be repositioned or withdrawn back into the angiographic catheter, if required.
5. With coil positioned in its desired location, remove safety lock from the coil positioner catheter.
6. Depress proximal button on the coil positioner catheter to effect coil release.
7. Remove coil positioner catheter, wire and loading cartridge from angiographic catheter.
8. Verify adequate position in the vessel.

~~1~~

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**Premarket Notification
Coil Positioner Set**

**Appendix H
Substantial Equivalence Data**

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TABLE 1: COMPARABLE PREDICATE DEVICES

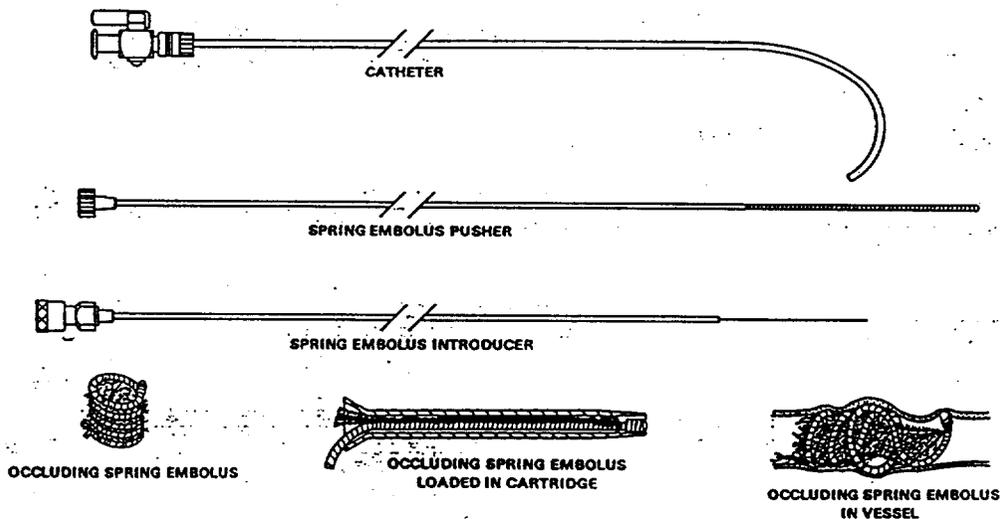
Characteristics	COOK INCORPORATED Coil Positioner Set	COOK INCORPORATED Embolization Coils Order #MWCE-X-X-X Pre-amendment & D.C.#K901337	COOK INCORPORATED Embolization Set Order #GA0-1 Pre-Amendment D.C.#K914786	Target Therapeutics Embolization Coils Order #332XXX.#522XXX D.C.#K914786
Indications	Arterial and Venous Embolization	Arterial and Venous Embolization	Arterial and Venous Embolization	Arterial and Venous Embolization
Method of Introduction	Percutaneous Using Catheter Introducer	Percutaneous Using Catheter Introducer	Percutaneous Using Catheter Set	Percutaneous Using Catheter Introducer
Coil Material(s)	Stainless Steel and Synthetic Fiber	Stainless Steel and Synthetic Fiber	Stainless Steel & Cotton, Wool & Synthetic Fiber	Platinum and Synthetic Fiber
Size	0.018 to 0.038-inch Same as MWCE 2 to 20 mm	0.018 to 0.052-inch Curled & Straight 2 to 20 mm	0.021 to 0.035-inch Curled 4 to 7 mm	0.018 to 0.038-inch C-Shaped & Helical 2 to 10 mm
Coil Wire Diameter	0.018 to 0.038-inch	0.018 to 0.052-inch	0.021 to 0.035-inch	0.018 to 0.038-inch
Coil Shape	Same as MWCE	Curled & Straight	Curled	C-Shaped & Helical
Embol Size	2 to 20 mm	2 to 20 mm	4 to 7 mm	2 to 10 mm

Premarket Notification
Coil Positioner Set

**COMPARISON OF COOK COIL POSITIONER TO COOK PRE-AMENDMENT
GIANTURCO-WALLACE-ANDERSON EMBOLIZATION SET**

Page 91 from the 1976-77 COOK catalog is shown below to describe the components of the Gianturco-Wallace-Anderson Embolization Set. This device is similar to the Coil Positioner Set subject of this submission in its indications for use, in its raw materials, and its similar componentry (i.e., occluding spring embolus, spring embolus introducer, catheter and pusher). In combination with these similarities, the pre-Amendment device was packaged similarly to how the proposed device will be packaged and it will be exposed to a validated ETO sterilization cycle as was this pre-Amendment set. This pre-Amendment history provides reasonable assurance of safety and effectiveness as regards design validation, manufacturing, quality control and processing parameters of the proposed device since there are no new technological issues involved in this development.

GIANTURCO-WALLACE-ANDERSON ARTERIAL EMBOLIZATION SET
Sterile



Used for transcatheter embolization of visceral arteries.

Catalog number	Description
GAO-1	SET consists of 7 French catheter with matched pusher, introducer and ten occluding spring emboli. Complete description of components is listed below.
PWG-1	CATHETER AND SPRING EMBOLUS PUSHER. Catheter is 7 French radiopaque Teflon, 60.5 cm long.
EI-18-50	SPRING EMBOLUS INTRODUCER
WCE-35-5.7	OCCUDING SPRING EMBOLUS consists of 4 woolen strands, 3 cm long, attached to a 5 cm segment of tightly coiled stainless steel wire and enclosed in 7 French radiopaque Teflon cartridge.

References:

C. Gianturco, J. H. Anderson, S. Wallace: "Mechanical Devices for Arterial Occlusion," *American Journal of Roentgenology*, 124 (1975), 428-435.

S. Wallace, C. Gianturco, J. H. Anderson, H. M. Goldstein, J. L. Davis, R. L. Bree: "Transcatheter Intra-vascular Steel Coil Occlusion: Clinical Experience." Submitted for publication.

SUGGESTED INSTRUCTIONS FOR USING OCCLUDING SPRING EMBOLUS

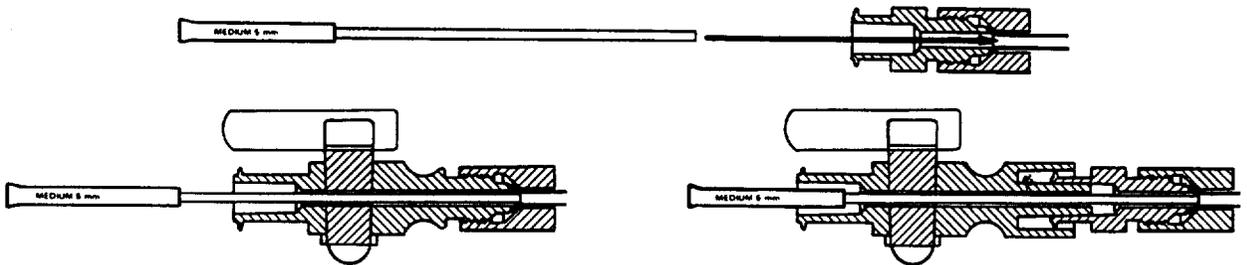
CATALOG NUMBER	Diameter of Coiled Spring Embolus mm	Color Code of Cartridge
MWCE-38-4-3	3	Black
MWCE-38-5-5	5	Blue
MWCE-38-5-8	8	Red

These occluding spring emboli are designed to be used with 6.5 French TORCON and 5.0M French (COOK) polyethylene catheters with tips tapered to a .038 inch (0.97 mm) wire guide.

To load the spring embolus into the catheter, insert the cartridge through the stopcock, hub, or both until it is seated on the catheter flare (see figures below). While maintaining the cartridge in this position, push the embolus into the catheter for a distance of 20-30 cm using the stiff end of a .038 inch (0.97 mm) wire guide. Remove the wire guide and cartridge.

With the soft tip of the wire guide, push the coil through the distal tip of the catheter. The ease with which the coil can be pushed through the terminal curve(s) of the catheter depends upon the flexibility of the wire guide tip. The Newton LLT (catalog number **SFNB-38-x**) is recommended for most cases; **SFNC** and **SLF** guides may be useful in some instances of excessive tortuosity of the vessels.

Gianturco, Wallace, and Chuang recommend that the last coil be positioned with particular care. This coil should not be left too close to the inlet of the artery and should be intermeshed with the previous coils if possible; it should be of sufficient size to wedge against the arterial walls. A minimal but sufficient arterial blood flow should remain to hold this coil against the previous coils or other embolic materials until a solid clot insures a permanent fixation. The purpose of these recommendations is to minimize the possibility of a loose coil becoming dislodged and obstructing a normal and essential arterial channel.



NOTICE
 If a catheter with sideports is used, the embolus may jam in the sideport or pass through it into a location other than that intended.

REFERENCE

V. P. Chuang, S. Wallace, C. Gianturco: "A New Improved Coil for Tapered Tip Catheter for Arterial Occlusion," *Radiology*, 135 (1980), 507-509.

COOK®

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 A COOK GROUP COMPANY
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 Phone: 812 339-2235

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HILAL EMBOLIZATION MICROCOILS™

CURLED

Used for embolization of selective vessel supply to tumors, arterio-venous malformations and other vascular lesions. Design of the Microcoils™ permits introduction through small pre-positioned delivery catheters. Deployment of coils into the vessel lumen is accomplished utilizing standard wire guide pusher techniques. The coils are made of platinum, easily detected radiographically, with spaced synthetic fibers to promote maximum thrombogenicity. **NOTE:** Microcoils™ may be used with particulate or liquid embolization materials. Supplied sterile in peel-open packages. Intended for one-time use.



ORDER NUMBER	Curled Diameter	Length	Configuration	Remarks
MWCE-18-1.0-3-HILAL	3 mm	1.0 cm	Curled	Supplied 2 each per package
MWCE-18-1.5-5-HILAL	5 mm	1.5 cm	Curled	
MWCE-18-2.1-7-HILAL	7 mm	2.1 cm	Curled	
MWCE-18-3.0-10-HILAL	10 mm	3.0 cm	Curled	

Positioning of Microcoils™ should be done with particular care. Microcoils™ should not be left too close to the inlets of arteries and should be intermeshed with previously placed Microcoils™ if possible. A minimal but sufficient arterial blood flow should remain to hold the Microcoil™ against the previously placed Microcoils™ until a solid clot insures permanent fixation. The purpose of these suggestions is to minimize the possibility of loose Microcoils™ becoming dislodged and obstructing a normal and essential arterial channel.

REFERENCES

S. Hilal, M.D., Department of Radiology, The Neurological Institute, New York, New York.

S. Hilal, et al: "Synthetic Fiber Coated Platinum Coils Successfully Used for the Endovascular Treatment of Arterio-Venous Malformations, Aneurysms, and Direct Arterio-Venous Fistulae of the Central Nervous System," Scientific paper presented at the 26th Annual Meeting of the American Society of Neuroradiology, Chicago, Illinois, May, 1988.

V. P. Chuang, S. Wallace, C. Gianturco: "A New Improved Coil for Tapered Tip Catheter for Arterial Occlusion," *Radiology*, 135 (1980), 507-509.

HILAL EMBOLIZATION MICROCOILS™

STRAIGHT

Used for embolization of selective vessel supply to arterio-venous malformations and other vascular lesions of the brain, spinal cord, spine and other small vessel applications. Design of the Microcoils™ permits introduction through small, pre-positioned delivery catheters. Unique, straight, non-curling 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.



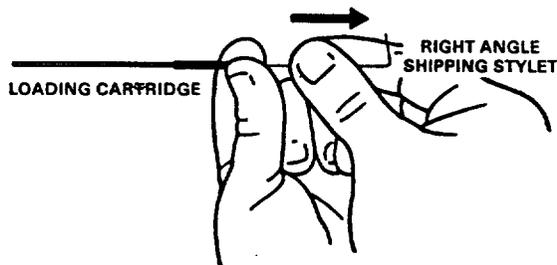
ORDER NUMBER	Length ¹	Configuration	Remarks
MWCE-18-0.5-0-HILAL	.5 cm	Straight	
MWCE-18-0.7-0-HILAL	.7 cm	Straight	
MWCE-18-1.0-0-HILAL	1.0 cm	Straight	Supplied 2 each per package
MWCE-18-1.5-0-HILAL	1.5 cm	Straight	

¹Other 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 non-tapered T3.0 and T3.0S Teflon® catheters.
- Microcoils™ are not recommended for use with polyurethane or polyvinylchloride catheters.
- Wire guides recommended for loading and positioning Microcoils™ are Teflon® coated .018 inch (0.46 mm) diameter with flexible tapered tips. **NOTE:** Cook Order Numbers: **TSFNA-18-180, TSFNB-18-180.**

TO LOAD MICROCOIL™ INTO DELIVERY CATHETER



1. Firmly grasp Microcoil™ loading cartridge between thumb and forefinger at point where right angle shipping stylet exits.
2. While maintaining firm finger grip, remove shipping stylet. This will prevent Microcoil™ from exiting cartridge. Verify its position inside cartridge by direct vision.

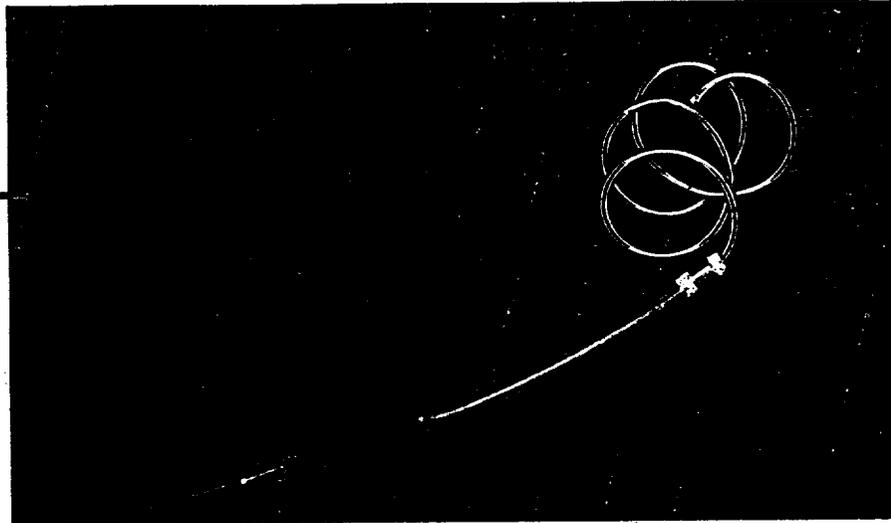


3. Position loading cartridge into base of hub of catheter.



4. Using .018 inch (0.46 mm) diameter wire guide, push Microcoil™ out of loading cartridge and into catheter lumen.
5. Remove loading cartridge.

COMPLEX HELICAL
PLATINUM COILS
VASCULAR
OCCCLUSION SYSTEM



APPPLICATIONS

- The occlusion system, used in conjunction with a Tracker®-18 Catheter, allows selective delivery of Platinum Coils to the smallest vasculature. The Platinum Coils are indicated for preoperative vaso-occlusion and site

specific flow reduction of vascular abnormalities in the central nervous system:

- Arteriovenous malformations
- Arteriovenous fistulas

FEATURES

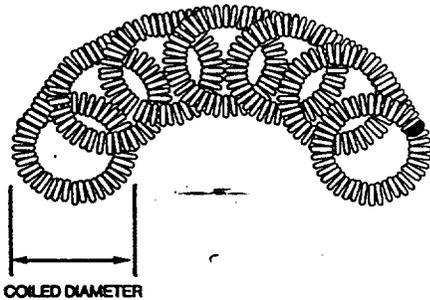
- Platinum Coils are non-ferromagnetic.
- Complex helical design reduces dead space evident in single helical coils.
- Spatial filling of selected vasculature by radiopaque platinum.
- Polished, soft coil tip lessens likelihood of vessel wall trauma.

- Coil Pusher-16 improves control during coil delivery.
- Laminated polymer surface on pusher reduces friction with the Tracker-18.
- Radiopaque gold-tipped marker on Coil Pusher-16 allows fluoroscopic visualization.
- Available in a wide variety of sizes.



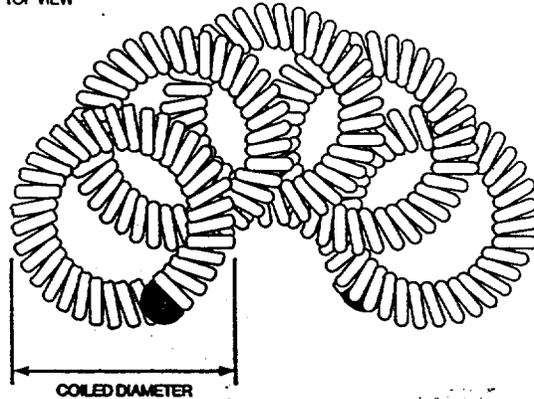
**COMPLEX HELICAL
PLATINUM COILS
VASCULAR
OCCLUSION SYSTEM**

TOP VIEW



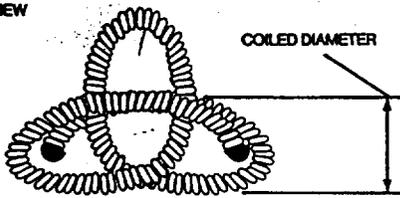
COIL PRODUCT NO. 311024

TOP VIEW



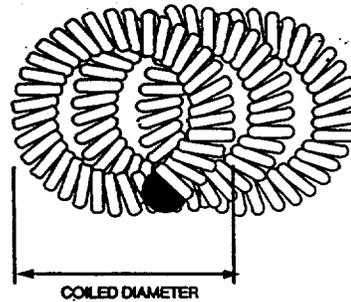
COIL PRODUCT NO. 311046

TOP VIEW



COIL PRODUCT NO. 311022

TOP VIEW



COIL PRODUCT NO. 311043

Drawings are not shown to scale.

SPECIFICATIONS

Kit Product No.	Coil Product No.	Coiled Diameter (mm)	Length in Introducer (cm)*
520024	311024	2	4
520046	311046	4	6
520022	311022	2	2
520043	311043	4	3

*Straight length of coil in introducer.



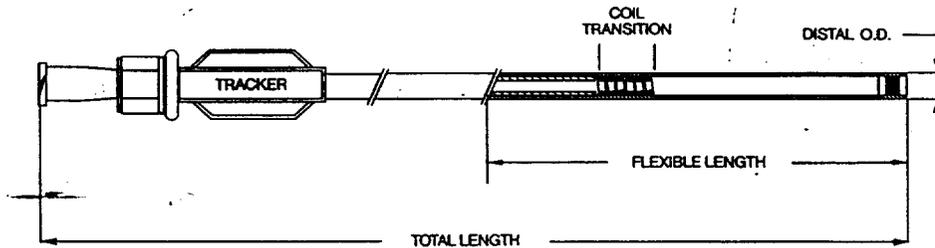
130 Rio Robles San Jose, CA 95134-1806

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118.

TRACKER®-18 LF INFUSION CATHETER

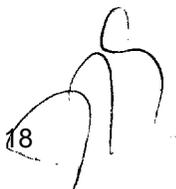


A PPLICATIONS

- o Positive access to the smallest vasculature, the Tracker systems are essential for:
 - Subselective angiography
 - Embolization of distal vascular anomalies
 - Site specific thrombolytic therapy
 - Crossing vascular lesions in tortuous pathways

F EATURES

- o The LF is the "next step in Tracker technology."
- o Coaxial microcatheter may be used with all angiographic/guiding catheters which will accept 0.038 in. guide wires.
- o Radiopaque distal platinum tip for easy visualization under conventional fluoroscopy and digital subtraction angiography (DSA).
- o Decreased luminal friction for increased trackability.
- o Platinum coil transition zone protects inner luminal surface from substantial guide wire manipulation and intermittent high pressure injections.
- o Coil transition zone reduces likelihood of kinking where distal tip begins.
- o Radiopaque platinum coil provides an increased visualization zone.



TRACKER®-18 LF
INFUSION
CATHETER

SPECIFICATIONS

Catheter No.	Coil Transition Length (cm)	Total Length/ Flexible Length (cm)	Minimum Guiding Catheter ID
123201	2.0	150/25	0.038 in./1.00 mm

TECHNICAL NOTES

- o Compatible with all angiographic catheters which will accept 0.038 in. guide wires.
- o Compatible with Target Therapeutics' platinum coils for occlusion.
- o Proximal OD 3F/0.039 in./1.00 mm
Distal OD 2.2F/0.029 in./0.89 mm
Coil Transition OD 2.8F/0.035 in.
- o Designed for use with Target Therapeutics' steerable guide wire less than or equal to 0.016 in. in diameter.

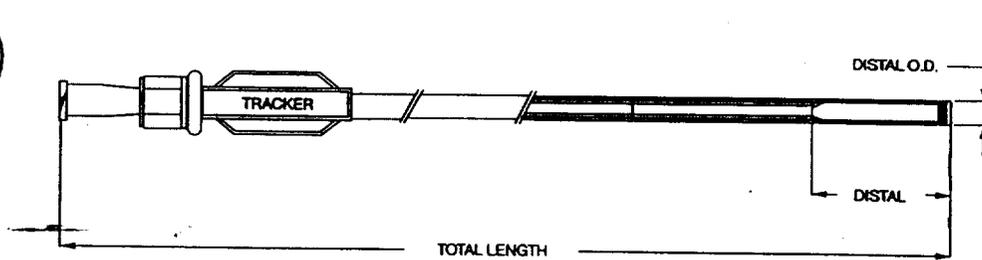


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TRACKER®-18

INFUSION CATHETER



APPPLICATIONS

- Positive access to the smallest vasculature, the Tracker system of microcatheters are essential for:
 - subselective angiography
 - embolization of distal vascular anomalies
 - site specific thrombolytic therapy
 - chemoembolization and drug delivery
 - crossing vascular lesions in tortuous pathways

FEATURES

- Most widely used Tracker Infusion Catheter.
- Coaxial microcatheter may be used with all angiographic/guiding catheters which will accept 0.038 in. guide wire.
- Radiopaque distal platinum tip for easy visualization under conventional fluoroscopy and digital subtraction angiography (DSA).
- Available in Vascular Access System kits (VAS).



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TRACKER®-18

INFUSION

CATHETER

SPECIFICATIONS

Kit No.	Catheter No.	Total Length/Distal Section (cm)	Minimum Guiding Catheter ID
503102	103102	150/12	0.038 in./1.00 mm
503111	103111	150/18	0.038 in./1.00 mm
503107	103107	135/12	0.038 in./1.00 mm
503119	103119	60/12	0.038 in./1.00 mm
513111 (contains Seeker® 14)		150/18	0.038 in./1.00 mm

TECHNICAL NOTES

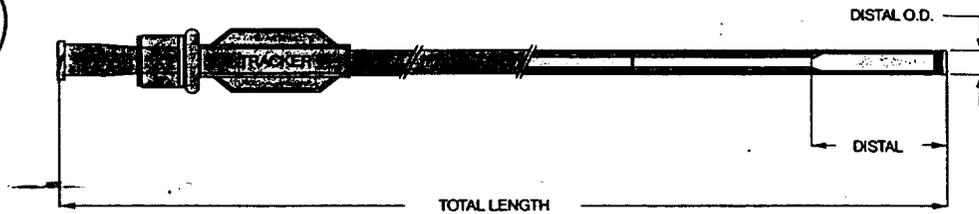
- o Most widely used Tracker Infusion Catheter.
- o Compatible with all angiographic/guiding catheters which will accept 0.038 in. guide wires.
- o Compatible Tracker for use with Target Therapeutics' platinum coils for occlusion.
- o Available in 5 mm and 20 mm extended tips.
- o Proximal OD 3F/0.039 in./1.00 mm
Distal OD 2.2F/0.029 in./0.89 mm
Proximal ID NA/0.022 in./0.56 mm
Distal ID NA/0.021 in./0.53 mm
- o Available in Vascular Access System kits (VAS), containing:
 - one Taper™-16 steerable guide wire or Seeker Standard 14 and Guide Wire Introducer
 - one Tracker®-18 and one Rotating Hemostatic Valve
- o Designed for use with Target Therapeutics' steerable guide wires equal or less than 0.016 in. diameter.
- o See system set-up for additional recommendations.



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 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

TRACKER®-25
INFUSION
CATHETER



APPLICATIONS

- Positive access to the smallest vasculature, the Tracker system of microcatheters are essential for:
 - subselective angiography
 - embolization of distal vascular anomalies
 - site specific thrombolytic therapy
 - chemoembolization and drug therapy
 - crossing vascular lesions in tortuous pathways

FEATURES

- Higher flow rates and easier injection of diagnostic and therapeutic agents.
- Larger embolic materials delivered.
- Graded shaft stiffness tapers from 4.0F to 3.6F distal platinum tip.
- Radiopaque distal platinum tip offers visualization under conventional fluoroscopy and digital subtraction angiography (DSA).
- Coaxial microcatheter used with 6.5F or 7.0F nontapered angiographic guiding catheters.
- Available in Vascular Access System kits (VAS).



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TRACKER[®]-25

INFUSION

CATHETER

SPECIFICATIONS

Kit No.	Catheter No.	Total Length/Distal Section (cm)	Minimum Guiding Catheter ID
506107	106107	150/18	0.054 in./1.37 mm
506104	105104	135/12	0.054 in./1.37 mm

TECHNICAL NOTES

- o Higher flow rates:
 - 100 PSI, 60% contrast (2cc/sec.)
 - Compatible with intra-arterial and intravenous infusion pumps
- o Easier for delivery of embolic materials such as:
 - 0.025 in. micro-coils
- o Proximal OD 4F/0.052 in./1.32 mm
 Distal OD 3.6F/0.046 in./1.17 mm
 Proximal ID NA/0.031 in./0.79 mm
 Distal ID NA/0.028 in./0.71 mm
- o Available in Vascular Access System kits (VAS), containing:
 - one Taper[™]-22 steerable guide wire and Guide Wire Introducer
 - one Tracker-25 and one Rotating Hemostatic Valve
- o Compatible with angiographic/guiding catheters with 0.054 in. distal internal diameter.
- o See system set-up for additional recommendations.



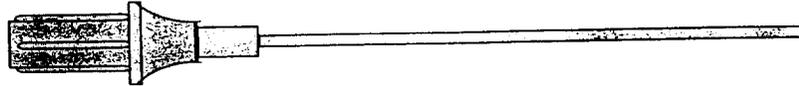
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ACCESSORIES



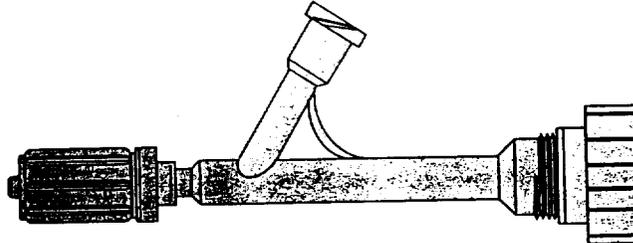
GUIDE WIRE INTRODUCER

- o Facilitates passage of pre-shaped guide wire through Rotating Hemostatic Valve into catheter.
- o Protects guide wire distal platinum coil tip.
- o See system set-up for additional recommendations.



TORQUE DEVICE

- o Pin vise attached to proximal end of guide wire facilitates smooth, accurate positioning of guide wire distal tip.
- o Two piece design configuration.



ROTATING HEMOSTATIC VALVE (RHV)

- o A transparent rotating Tuohy-Borst adaptor with an adjustable valve provides a fluid tight seal between catheters, guiding catheters and guide wires.
- o Allows continuous flush between angiographic catheter and Tracker* or between Tracker and guide wire.
- o Inside diameter: 0.054 in./4.F.
- o See system set-up for additional recommendations.

PRODUCT NUMBER

422290 Guide Wire Introducer for 0.010 in. to 0.018 in. guide wires. Included with all guide wires.

423242 Rotating Hemostatic Valve. Included with all Tracker* catheters.



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Questions? Contact FDA/CDRH/OCE/DIV 13 at CDRH, FOIA STATUS Office, 1-800-352-8431 or 301-796-8418