Records processed under FOIA Request 2014-7435; Released 10/23/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

Mr. Armand Hamid
EXEL® International Co.
Medical Products Division
P.O. Box 3194
CULVER CITY CA 90231-3194

Re: K013037
Trade/Device Name: EXEL A.V. Fistula Needle
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 FIE
Dated: August 31, 2001
Received: September 10, 2001

Dear Mr. Hamid:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

510(k) Number (if known): K013037

Device Name: EXEL A.V FISTULA NEEDLE SET

Indications For Use:

THIS DEVICE IS AN A.V. FISTULA NEEDLE SET PART OF EXTRACORPORIAL ARTIFICAL KIDNEY SYSTEM FOR THE TREATMENT OF PATIENTS WITH RENAL FAILURE TO PROVIDE ACCESS TO THE PATIENT'S BLOOD VESSEL FOR HEMODIALYSIS.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Ilegerm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013037

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

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reviewed by BIM SE 12/7/2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 12-17-01

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K013037/A3

To: Division Director: GU/DRARD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____Additional information requires a new 510(k); however, the information submitted is incomplete; (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

_____Additional information requires a new 510(k); please process [This information will be made into a new 510(k)

___✓___No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

____Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: Dmc Cal

Date: 1/8/02

Draft #2 : 9/8/99
Draft #3: 1/3/00

C Newland
1/16/02

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

K 013037/1/3

EXEL INT®
INTERNATIONAL CO.

TÜV PRODUCT SERVICE

December 7th, 2001

Ms. Barbara McCool
U.S. Food & Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) No.: K013037
EXEL A.V. Fistula Needle

Dec 17 9 57 AM '01

Dear Ms. McCool,

Hope everything is going well for you. Thanks for your today's phone call.

Please be informed that both (Exel & Bioteque) A.V. Fistula Needles has the same manufacturing process of producing this product.

As mentioned previously the only difference is the shape of the wing.

Hope everything is satisfactory for you in obtaining our 510(k) approval.
If any question, please let us know.

Best regards.

Navid Hamid for Armand Hamid

AH/te

INTERNATIONAL HEADQUARTERS
MEDICAL PRODUCTS DIVISION
All Mail to: P.O. BOX 3194, Culver City, California 90231-3194
Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1168 Bank: City National Bank
e-mail: exelmed@exelmed.com

SKS

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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DEC 0 7 2001

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

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Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

510(k) Number (if known): K013037

Device Name: EXEL A.V FISTULA NEEDLE SET

Indications For Use:

THIS DEVICE IS AN A.V. FISTULA NEEDLE SET PART OF EXTRACORPORIAL ARTIFICAL KIDNEY SYSTEM FOR THE TREATMENT OF PATIENTS WITH RENAL FAILURE TO PROVIDE ACCESS TO THE PATIENT'S BLOOD VESSEL FOR HEMODIALYSIS.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Ostergard

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013037

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

3

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

12/7/01

From: Reviewer(s) - Name(s) B McCool

Subject: 510(k) Number K013037

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☒ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

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

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

☐ The required certification and summary for class III devices NA

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

Material of Biological Origin ☐ YES ☒ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 21 CFR 876.5540 Class II 78 FIE

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

Review: [signature] for CYN (Branch Chief) GRDB (Branch Code) 12/7/01 (Date) [signature]

Final Review: [signature] (Division Director) 12/7 (Date)

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Revised:8/17//99

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

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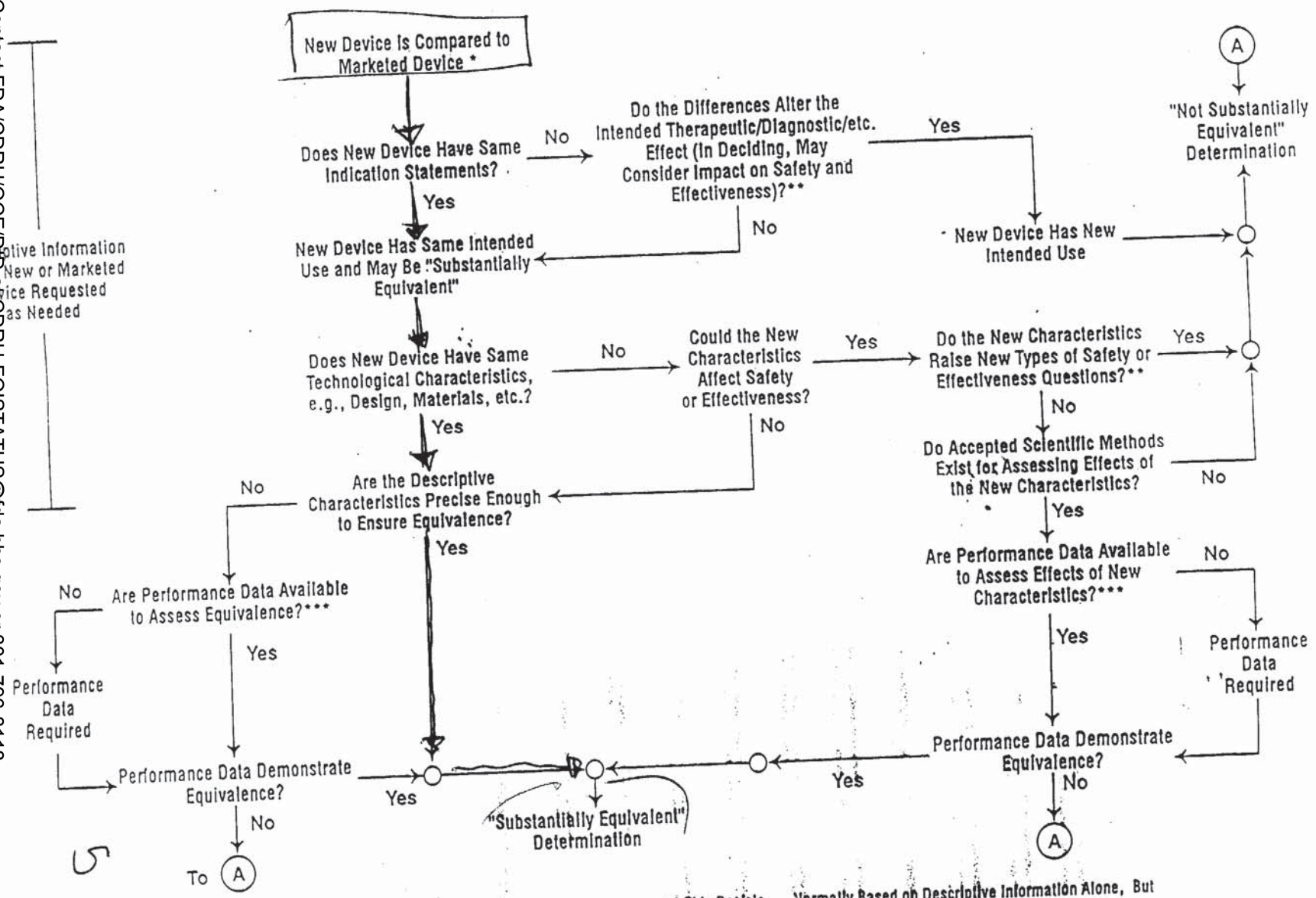
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



5

* 510(k) Submiss ... ompare New Devices to Marketed Devices. FDA Requests Additional Infor ... If the Relationship Between Marketed and "Predicate"

** This Decisio ... Normally Based on Descriptive Information Alone, But Limited Tes ... Information Is Sometimes Required.

*** Data May Be ... the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

Memorandum

Date: December 4, 2001

From: Barbara McCool, RN MS
Gastroenterology and Renal Devices Branch, HFZ-470

Subject: EXEL Arterial Venous Fistula Needle K013037

"SUBSTANTIAL EQUIVALENCE" (SE)
DECISION-MAKING DOCUMENTATION

Reviewer: **Barbara McCool, RN, MS**
Division/Branch: DRARD/GRDB, HFZ-470

Trade Name: EXEL Arterial Venous Fistula needle

510(k) Number: K013037

Manufacturer: (b)(4) contractor [redacted]

Common Name: AV Fistula Needle

Classification: 21 CFR §876.5540 Class II, ProCode 78 FIE

Product To Which Compared: BIOTQUE Fistula Needle Set (K993118)
EXELINT Fistula Needle Set (K001496)

Contact: Armand Hamid, Director EXELINT International Co.

Phone: (310) 649-0707

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

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	YES	NO*	
1. IS PRODUCT A DEVICE?	X		IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	X		IF NO STOP
3. SAME INDICATION STATEMENT?	X		IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?		X	IF YES STOP → NSE
5. SAME TECHNOLOGICAL CHARACTERISTICS		X	IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?		X	IF YES STOP → SE IF NO GO TO 10
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			IF YES STOP → NSE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			IF NO STOP → NSE
10. PERFORMANCE DATA AVAILABLE?			IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?			

* **"yes"** responses to 4, 6, 8, and 11, and every "**no**" response requires an explanation below

Device Description:

The fistula needle has a stainless steel cannula, plastic tubing, plastic clamp and a female luer lock connector universal connection with bloodlines. It is a nonimplanted device. All of the needles have oval back eye (slit) for better blood flow. The wing type is provided with either a fixed or a rotating head. The firm has 4 variations of fistula needles (which range in needle size

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

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and lengths from 14G to 17G and length is either 1 inch or 1 and a quarter inch).

In compliance with the SMDA of 1990, the sponsor has included a statement that safety and effectiveness information upon determination of the substantial and equivalence was based will be made available upon request.

Life-supporting or life sustaining:	NO
Implant (short or long term):	NO
Software driven:	NO
Sterile:	YES
Patient Contacting Device:	YES
Single Use:	YES
Home Use:	NO
Prescription Use:	YES
Drug or Biological Product:	NO
Kit	NO

Recommendation:

I recommend that the proposed device be found substantially equivalent to other legally marketed devices as described in 21 CFR §876.5540 Class II, ProCode 78 FIE, Non-implanted Blood Access Device and Accessories.

BM c Cool

Barbara McCool, RN, MS

Date: 12/4/01

Note: In a telephone conversation with Navie Hamid of Excel International, Mr. Hamid confirmed that the proposed A.V. Fistula needle, manufactured by Taijin Haraco Medical, has identical manufacturing process as the predicate needle, manufactured by Biotegue. Only change is in the manufacturing site.

for CYN 12/7/01

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

MEMORANDUM

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
DRAERD/ADOU/GRDB

Date: December 4, 2001

From: Barbara McCool, RN, MS
Gastroenterology and Renal Devices Branch, HFZ-470

Subject: AV Fistula Needle
K0103037/A1

To: The Record

Background:

EXELINT submitted a premarket notification for a fistula needle. This is my first review of the submission. After contacting Armand Hamid, Director of EXELINT International (see attachments), the firm Faxed in the additional information and identified two predicates for this proposed device. One of their predicates was their own cleared A-V fistula needle (K903945). The other device was manufactured by BIOTEQUE Corporation which I reviewed and was cleared on 2 February 2000 under 510K No 993118. The only difference in this device is that Tianjin Hanaco Medical Co., Ltd., in Tianjin/China will manufacture it.

Intended Use:

This device consists of a (AVF) arterial fistula needle which is inserted into a patient's arterial side of their access to draw blood into an extracorporial system and back into the patient's venous side of their access via a venous fistula needle during hemodialysis.

Indications for Use:

This device is a AV fistula needle set (part of the extracorporeal artificial kidney system) for the treatment of patients with renal failure to provide access to a patient's blood vessel for hemodialysis.

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

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Device Description:

The fistula needle has a stainless steel cannula, plastic tubing, plastic clamp and a female luer lock connector universal connection with bloodlines. It is a nonimplanted device. All of the needles have oval back eye (slit) for better blood flow. The wing type is provided with either a fixed or a rotating head. The firm has 4 variations of fistula needles (which range in needle size and lengths from 14G to 17G and length is either 1 inch or 1 and a quarter inch).

Predicate Device:

510k No. K001496 (manufactured by EXEL International and 510k No: K993118 (manufactured by BIOTEQUE corporation, located in Taiwan).

General Information Summary:

Life-supporting or life sustaining:	NO
Implant (short or long term):	NO
Software driven:	NO
Sterile:	YES
Patient Contacting Device:	YES
Single Use:	YES
Home Use:	NO
Prescription Use:	YES
Drug or Biological Product:	NO
Kit	NO

Submission Provides:

Comparative Specifications:	YES
Bench Data	NO
Summary of Animal Testing:	NO
Summary of Clinical Testing:	NO
510(k) Statement:	YES
510(k) Summary:	NO
Truthful and Accurate Statement:	YES
Indications for Use Statement:	YES

Sterility:

(b)(4) sterility

[redacted]

10

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

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Pyrogen Testing:

Pyrogen free done by the (b)(4) testing [redacted]

Patient Contacting Materials:

The patient contacting part is the sterile stainless steel needle.

Biocompatibility:

The proposed device contains the exact material as their legally marketed predicate device and meets the standard as outlined in ISO 10993.

Labeling:

The device is labeled as sterile, non pyrogenic, for single use only, and has a prescription statement.

Expiration Dating:

None Claimed

Bench Testing:

It is identical to their own predicate device which included static tensile force of all connections between all components, air tightness traction, sealing pressure, pull-out strength, aging testing, and internal specs for needle penetration, drilling and flowing force, and needle rotation.

Proposed Classification:

78, Class II, CFR 876.5540, FIE

Recommendation:

I recommend that the proposed device be found substantially equivalent to other legally marketed devices as described in 21 CFR §876.5540, Class II, ProCode FIE.

BMc Cool

Barbara McCool, RN, MS Date: 12/4/01

for CYN

Concur: Carolyn Neuland, PhD Date: 12/7/01

11

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

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FAX COVER PAGE

5840 W. CENTINELA AVENUE, LOS ANGELES CA 90045
TEL: (310) 649-0707 * FAX: (310) 649-1178

[redacted]

Fax

TO: U.S. FDA/CDRH/ODE

FROM: Navid Hamid

ATTN: Ms. Barbara McCool

DATE: 12/7/01

REF.: 510(k) Submissions

CC :

FAX.: 301-594-2339

PAGES: 3 INCLUDING COVER PAGE

Dear Ms. McCool,

Attached please find both letters that you requested for manufacturing process for both items are the same and the product is same for Shargh.

If any question, please let us know.

Best regards.

12

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

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EXEL®
INTERNATIONAL CO.

TÜV

December 7th, 2001

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Navid Hamid for Armand Hamid

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INTERNATIONAL HEADQUARTERS
MEDICAL PRODUCTS DIVISION
All Mail to: P.O. BOX 3194, Culver City, California 90231-3194
Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1168 Bank: City National Bank
e-mail: exelmed@exelmed.com

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Records processed under FOIA Request 2014-7435; Released 10/23/14

K013037/A2

EXEL® INTERNATIONAL CO.

TÜV

November 27th, 2001

Ms. Barbara McCool
U.S. Food & Drug Administration
Office of Device Evaluation
Document mail center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

RECEIVED DEC 4 12 39 PM '01 FDA CDRH/OCE/DID

Re: 510(k) No.: K013037
EXEL A.V. Fistula Needle

Dear Ms. McCool,

Hope everything is going well for you. Thanks for your phone call today.

Enclosed please find copy of our letter to you dated Oct. 31st and certified mail receipt stamped Nov. 1st.

Please be kind to acknowledge this package upon receipt.

Thanking you in advance for your kind help and attention. If any questions, please feel fee to contact me at (310) 649-0707 ext. 12.

Best regards.

Tammie Ewing

Tammie Ewing
Exel Medical Products

TE/bs
Encl:

INTERNATIONAL HEADQUARTERS
MEDICAL PRODUCTS DIVISION
All Mail to: P.O. BOX 3194, Culver City, California 90231-3194
Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1168 Bank: City National Bank
e-mail: exelmed@exelmed.com

Sp 4

14

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Records processed under FOIA Request 2014-7435; Released 10/23/14

EXEL®
INTERNATIONAL CO.

TÜV

October 31st, 2001

Ms. Barbara McCool
U.S. Food & Drug Administration
Office of Device Evaluation
9200 Corporate Blvd
Rockville, MD 20850

Re: 510(k) No.:K013037
EXEL A.V. Fistula Needle

Dear Ms. McCool,

Hope everything is going well for you.

Based on our phone conversation, I am forwarding the pertinent information as you had requested for our A.V. Fistula Needle registration.
(Comparison Data per our 510k No.: K001496).

I hope this information meets your satisfaction for approval of our new 510k No.: K013037.

As always thanking you in advance for your kind help and attention. Please do not hesitate to contact me with any questions.

Best regards.

Armand Hamid
EXEL International Co.

AH/te
Encl:

7000 1670 0008 1356 9656

ROCKVILLE MD 20850

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Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1168 Bank: City National Bank
e-mail: [illegible]@exelinc.com

15

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

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4. Configuration of the Device	See attachment	Identical
5. Bio-compatibility	See attachment	Identical
6. Physical Test	See attachment 2	Identical
7. Chemical test	See attachment 3	Identical
8. Sterilization Method	(b)(4) sterilization	(b)(4) sterilization
9. SAL		
10. Pyrogenic	Pyrogen free Compatible to USP standards	Pyrogen free

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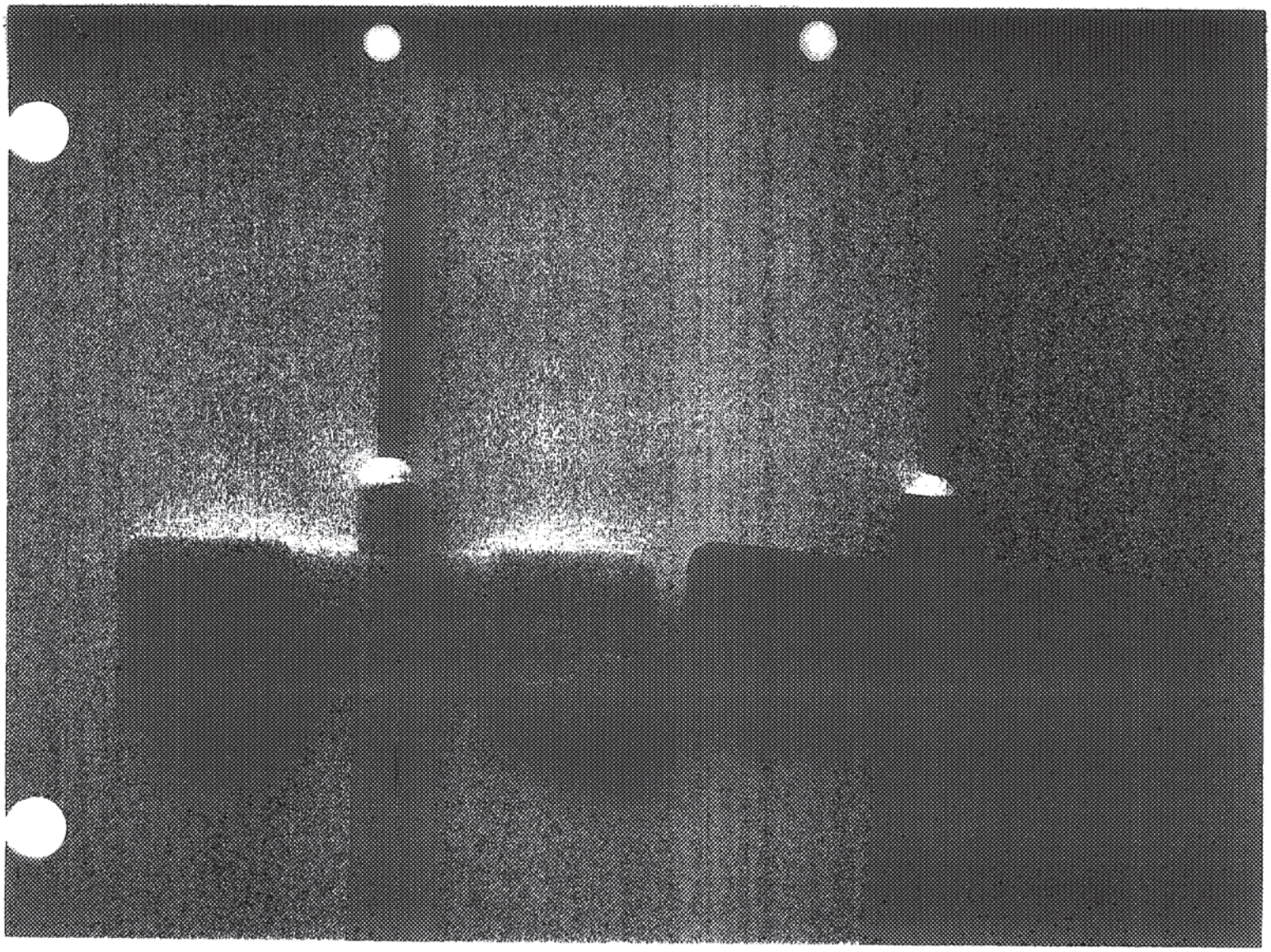

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EXEL®
INTERNATIONAL CO.

TÜV

August 3rd, 2000

Food and Drug Administration
Office of Device Evaluation
Attn.: Ms. Barbara McCool
Fax No: (301) 594-2339

RE: OUR 510K No: K001496 – EXEL A.V. FISTULA NEEDLE SET

Dear Ms. McCool,

I want to apologize for taking so much time to complete this and forward to you. Enclosed please find the additional request information about the difference between our A.V. Fistula Needle Set and BIOTEQUE'S A.V. Fislusta Needle Set.

Table 1: Comparison to Predicate Device

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2. Labeling	See attachment 5-1, 5-3 & 5-4	See attachment
3. Instruction for Use	See attachment 5-2	See attachment
4. Configuration of the Device	See attachment 1	Identical
5. Bio-compatibility	Compatible to ISO 10993 series standards (See attachment 4)	Identical
6. Physical Test	See attachment 2	Identical
7. Chemical test	See attachment 3	Identical
8. Sterilization Method	(b)(4) sterilization [redacted]	(b)(4) [redacted]
9. SAL	(b)(4) [redacted]	(b)(4) [redacted]
10. Pyrogenic	Pyrogen free Compatible to USP standards (See attachment 11)	Pyrogen free

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e-mail: exelmed@exelmed.com

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EXEL'S A.V. FISTULA

BIOTEQUE's A.V. FISTULA

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

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ATTACHMENT 1 (1/2)

BT-110(Series) A.V.FISTULA NEEDLE SPECIFICATION

APPEARANCE AND WEIGHT

1. 15GX 1 1/4" cannula length : 360+/ 20mm
2. 15G X 1" cannula length : 360+/ 20mm
3. 15G X 1 1/4" cannula weight : 6.7+/ 1g
4. 15GX 1" cannula weight : 6.7+/ 1g
5. Gap between connectors and tubes must not exceed 0.3mm

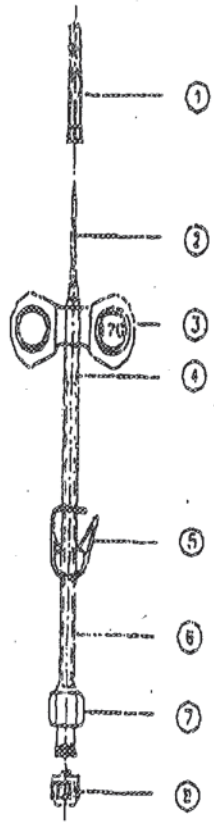
MODELS SPECIFICATION

BT-110 □□□-□□

- Artwork in numerical order
- C: Chinese ,E: English
- R: rotating wing
- B: with back eye
- A: 48mm cannula
- 15 G cannula

NOMENCLATURE

1. Protection cap
2. Needle
3. Yellow wings
4. Needle hub
5. Small clamp
6. PVC tube
7. Female luer lock
8. Luer lock cover



PHYSICAL TESTS

CNS K6139
BIOTEQUE STANDARDS
SIYOWA JUNE 20,58. No.494

CHEMICAL TESTS

SIYOWA JUNE 28,38 No. 494

BIOLOGICAL TESTS

1. Cytotoxicity : ISO 10993-5 92'
2. Sensitization : ISO 10993-10 95'
3. Acute Intracutaneous Reaction : ISO 10993-10 95'
4. Acute Systemic Toxicity: ISO 10993-11 93'
5. Pyrogen study : USP XXIII, 95'
6. Hemolysis : ISO 10993-4 93'

56

65

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ATTACHMENT 2

PHYSICAL TESTS SPECIFICATION

AIR TIGHTNESS:	No leakage than 2.5 kg/cm²
PULL-OUT STRENGTH:	Over 1.4 kgf/mm²
AGING TEST:	Perform all test after 70 ℃, 24hrs
WINTER HARDY:	Perform all test after -10 ℃, 6hrs

STICKING STRENGTH: Over 0.05kg/mm BIOTEQUE STANDARD

◆ The standard of static tensile force of connections between components as follows:

1. WING – FIXED TYPE

Parts (2) &(4) stress strength over 3.0 kg Parts (3) & (4) stress strength over 5.5 kg
Parts (4) & (6) stress strength over 4.5 kg Parts (6)&(7) stress strength over 7.0 kg

2. WING – ROTATING TYPE

Parts (2) & (4) stress strength over 3.0 kg Parts (4) &(6) stress strength over 4.5 kg
Parts (6) & (7) stress strength over 7.0 kg

◆ STAINLESS CANNULA LENGTH : 1) 15Gx 1" = 1.8x1.6x25mm
2) 15Gx 1 1/4" = 1.8x1.6x32 mm

◆ CURVATURE OF CANNULA : Should not exceed 0.031 mm

◆ STAIN COVERS SURFACE AREA : Should not exceed 0.3 mm²

◆ BURRS : Should not exceed 0.1 mm²

Product: A.V. FISTULA NEEDLE SET

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

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K 013037/R1

EXEL®
INTERNATIONAL CO.

TÜV

October 31st, 2001

Ms. Barbara McCool
U.S. Food & Drug Administration
Office of Device Evaluation
9200 Corporate Blvd
Rockville, MD 20850

FDA/CDRH/OEC/DID
NOV 9 11 35 AM '01
RECEIVED

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AH/te
Encl:

Received to GRDB on 12/5/01 after the fax of 11/30/01 BMcCol

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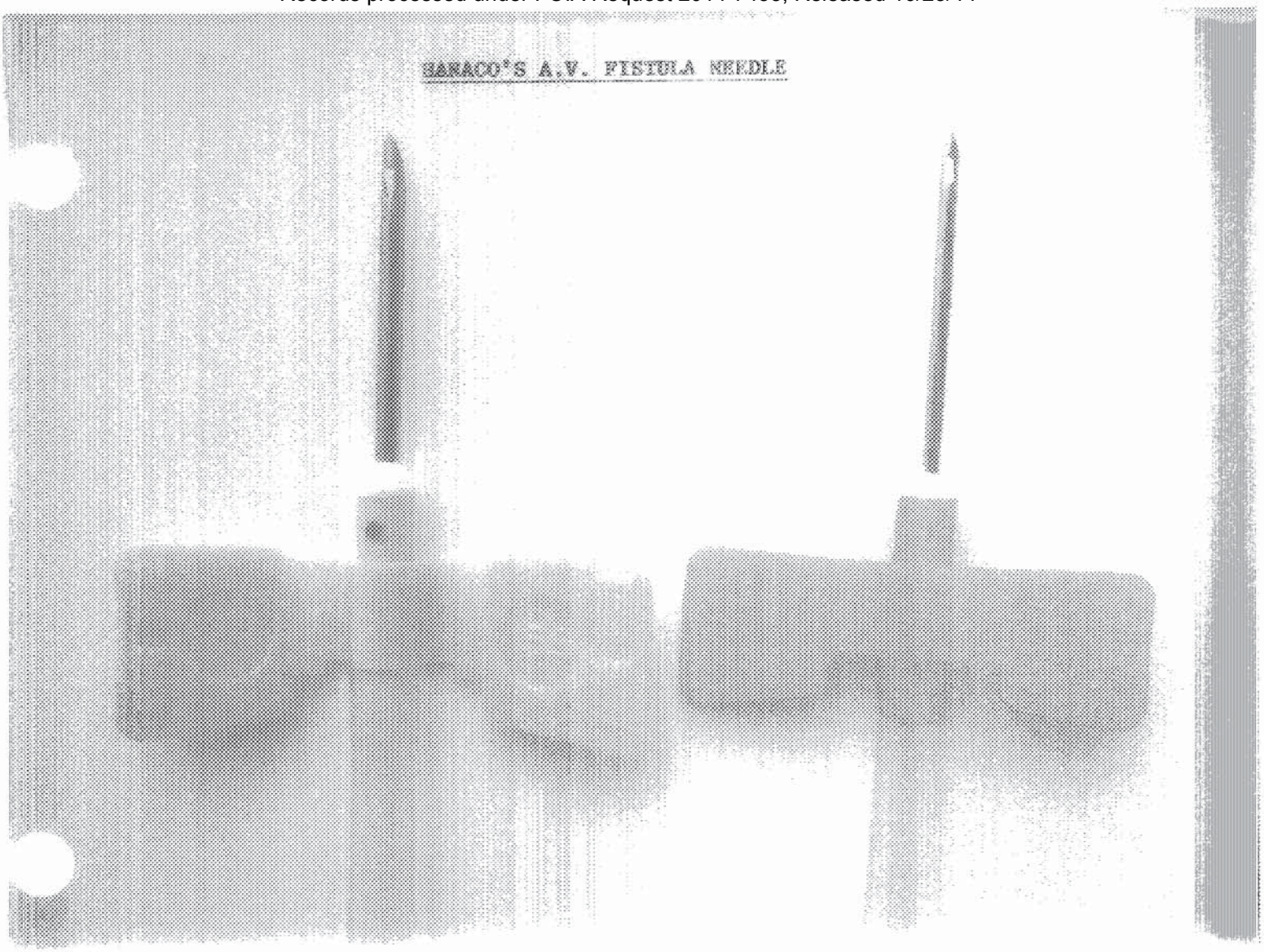
SARACO'S A.V. FISTULA NEEDLE



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TUV PRODUCT SERVICE

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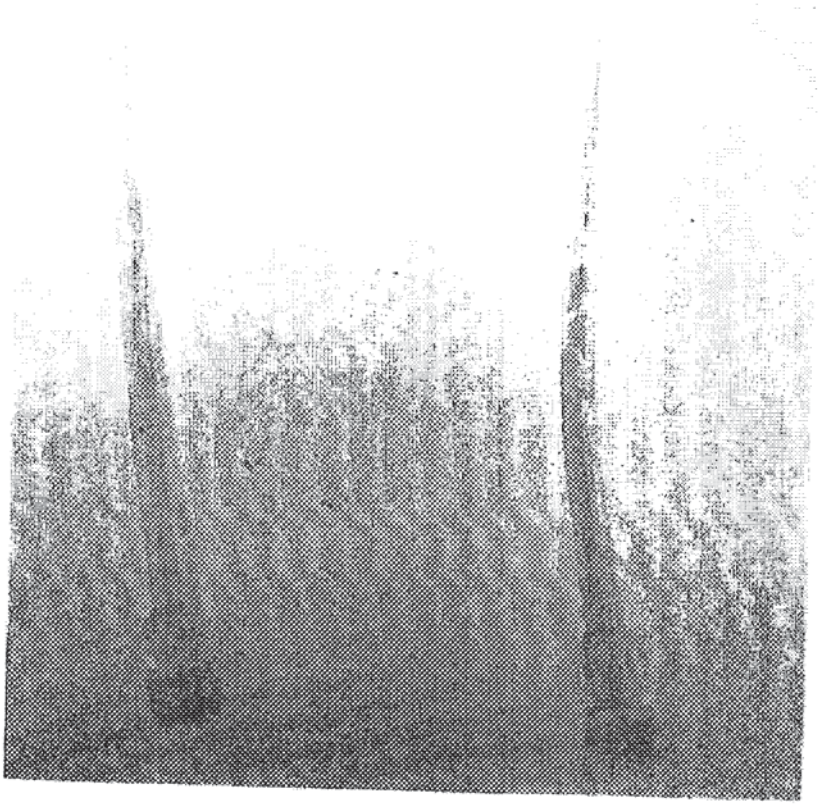

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BT-110(Series) A.V.FISTULA NEEDLE SPECIFICATION

APPEARANCE AND WEIGHT

1. 15GX 1 1/4" cannula length : 360+/ 20mm
2. 15G X 1" cannula length : 360+/ 20mm
3. 15G X 1 1/4" cannula weight : 6.7+/ 1g
4. 15GX 1" cannula weight : 6.7+/ 1g
5. Gap between connectors and tubes must not exceed 0.3mm

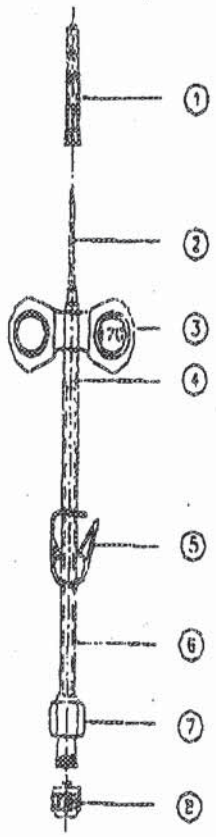
MODELS SPECIFICATION

BT-110 □□□-□□

- Artwork in numerical order
- C: Chinese ,E: English
- R: rotating wing
- B: with back eye
- A: 48mm cannula
- 15 G cannula

NOMENCLATURE

1. Protection cap
2. Needle
3. Yellow wings
4. Needle hub
5. Small clamp
6. PVC tube
7. Female luer lock
8. Luer lock cover



PHYSICAL TESTS

CNS K6139
BIOTEQUE STANDARDS
SIYOWA JUNE 20,58. No.494

CHEMICAL TESTS

SIYOWA JUNE 28,58 No. 494

BIOLOGICAL TESTS

1. Cytotoxicity : ISO 10993-5 92'
2. Sensitization : ISO 10993-10 95'
3. Acute Intracutaneous Reaction : ISO 10993-10 95'
4. Acute Systemic Toxicity: ISO 10993-11 93'
5. Pyrogen study : USP XXIII, 95'
6. Hemolysis : ISO 10993-4 93'

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

PHYSICAL TESTS SPECIFICATION

AIR TIGHTNESS:	No leakage than 2.5 kg/cm²
PULL-OUT STRENGTH:	Over 1.4 kgf/mm²
AGING TEST:	Perform all test after 70 ℃, 24hrs
WINTER HARDY:	Perform all test after -10 ℃, 6hrs

STICKING STRENGTH: Over 0.05kg/mm BIOTEQUE STANDARD

◆ The standard of static tensile force of connections between components as follows:

1. WING – FIXED TYPE

Parts (2) &(4) stress strength over 3.0 kg Parts (3) & (4) stress strength over 5.5 kg
Parts (4) & (6) stress strength over 4.5 kg Parts (6)&(7) stress strength over 7.0 kg

2. WING – ROTATING TYPE

Parts (2) & (4) stress strength over 3.0 kg Parts (4) &(6) stress strength over 4.5 kg
Parts (6) & (7) stress strength over 7.0 kg

◆ STAINLESS CANNULA LENGTH : 1)15Gx 1" = 1.8x1.6x25mm
2) 15Gx 1 1/4" = 1.8x1.6x32 mm

◆ CURVATURE OF CANNULA : Should not exceed 0.031 mm

◆ STAIN COVERS SURFACE AREA : Should not exceed 0.3 mm²

◆ BURRS : Should not exceed 0.1 mm²

Product: A.V. FISTULA NEEDLE SET

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

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FAX COVER PAGE

5840 W. CENTINELA AVENUE, LOS ANGELES CA 90045
TEL: (310) 649-0707 * FAX: (310) 649-1178

EXEL INTERNATIONAL CO.

Fax

TO: U.S. FDA

FROM: ARMAND HAMID

ATTN: MS. BARBARA McCOOL

DATE: 11/30/01

REF.: K013037

CC :

FAX.: (301) 594-2339

PAGES: 55 INCLUDING COVER PAGE

Dear Ms. McCool,

It was my pleasure speaking with you by phone.

As per your request enclosed please the additional information that you requested.

If any questions, please do not hesitate to let me know.

Regards.

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

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EXEL®
INTERNATIONAL CO.

TPV

November 27th, 2001

Ms. Barbara McCool
U.S. Food & Drug Administration
Office of Device Evaluation
Document mail center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510(k) No.: K013037
EXEL A.V. Fistula Needle

Dear Ms. McCool,

Hope everything is going well for you. Thanks for your phone call today.

Enclosed please find copy of our letter to you dated Oct. 31st and certified mail receipt stamped Nov. 1st.

Please be kind to acknowledge this package upon receipt.

Thanking you in advance for your kind help and attention. If any questions, please feel fee to contact me at (310) 649-0707 ext. 12.

Best regards.

Tammie Ewing

Tammie Ewing
Exel Medical Products

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MEDICAL PRODUCTS DIVISION
All Mail to: P.O. BOX 3194, Culver City, California 90231-3194
Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1168 Bank: City National Bank
e-mail: exelmed@exelmed.com

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INTERNATIONAL CO.

TÜV

October 31st, 2001

Ms. Barbara McCool
U.S. Food & Drug Administration
Office of Device Evaluation
9200 Corporate Blvd
Rockville, MD 20850

Re: 510(k) No.:K013037
EXEL A.V. Fistula Needle

Dear Ms. McCool,

Hope everything is going well for you.

Based on our phone conversation, I am forwarding the pertinent information as you had requested for our A.V. Fistula Needle registration.
(Comparison Data per our 510k No.: K001496).

I hope this information meets your satisfaction for approval of our new 510k No.: K013037.

As always thanking you in advance for your kind help and attention. Please do not hesitate to contact me with any questions.

Best regards.

Armand Hamid
EXEL International Co.

AH/te
Encl:

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City, State, ZIP+4 Rockville, MD 20850

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MEDICAL PRODUCTS DIVISION
All Mail to: P.O. BOX 3164, Culver City, California 90231-3164
Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1168 Bank: City National Bank
e-mail: exelmed@exelmed.com

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(b)(4) Third Party Test Data

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(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

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Table 1: Comparison to Predicate Device

ELEMENT OF COMPARISON	HANACO A.V. FISTULA NEEDLE SET	EXEL A.V. FISTULA NEEDLE SET
1. Intended Use(S)	The Arterial-Venous Fistula (A.V.F.) Needle Set consist of *arterial fistula needle*, which applies on the access site of patient's artery to draw the blood in to extra-corporeal system and back into the patient's vein via *venous fistula needle* during hemodialysis.	This device consist of *arterial fistula needle*, which is inserted into a patient's arterial side of their access to draw blood into an extra-corporeal system and back to the patient's venous side of their access via A.V. Fistula needle during Hemodialysis.
2. Labeling	See attachment	See attachment
3. Instruction for Use	Remove protection cap Insert needle into patients vein and allow all the air to outflow Connect Fistula needle to end connector of the arteriovenous line.	Idential
4. Configuration of the Device	See attachment	Identical
5. Bio-compatibility	See attachment	Identical
6. Physical Test	See attachment 2	Identical
7. Chemical test	See attachment 3	Identical
8. Sterilization Method	(b)(4) sterilization	(b)(4) sterilizatio
9. SAL		
10. Pyrogenic	Pyrogen free Compatible to USP standards	Pyrogen free

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

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EXEL® INTERNATIONAL CO.

TÜV

34/66

August 3rd, 2000

Food and Drug Administration
Office of Device Evaluation
Attn.: Ms. Barbara McCool
Fax No: (301) 594-2339

RE: OUR 510K No: K001496 – EXEL A.V. FISTULA NEEDLE SET

Dear Ms. McCool,

I want to apologize for taking so much time to complete this and forward to you. Enclosed please find the additional request information about the difference between our A.V. Fistula Needle Set and BIOTEQUE'S A.V. Fislusta Needle Set.

Table 1: Comparison to Predicate Device

ELEMENT OF COMPARISON	BIOTEQUE A.V. FISTULA NEEDLE SET (BT-110 Series)	EXEL A.V. FISTULA NEEDLE SET
1. Intended Use(S)	The Arterial-Venous Fistula (A.V.F.) Needle Set consist of *arterial fistula needle*, which applies on the access site of patient's artery to draw the blood in to extra-corporeal system and back into the patient's vein via *venous fistula needle* during hemodialysis. BIOTEQUE A.V. FISTULA NEEDLE SET is to be used by trained nurses or the doctors in the hemodialysis center.	This device consist of *arterial fistula needle*, which is inserted into a patient's arterial side of their access to draw blood into an extra-corporeal system and back to the patient's venous side of their access via A.V. Fistula needle during Hemodialysis.
2. Labeling	See attachment 5-1, 5-3 & 5-4	See attachment
3. Instruction for Use	See attachment 5-2	See attachment
4. Configuration of the Device	See attachment 1	Identical
5. Bio-compatibility	Compatible to ISO 10993 series standards (See attachment 4)	Identical
6. Physical Test	See attachment 2	Identical
7. Chemical test	See attachment 3	Identical
8. Sterilization Method	(b)(4) sterilizati	(b)(4) sterilizati
9. SAL		
10. Pyrogenic	Pyrogen free Compatible to USP standards (See attachment 11)	Pyrogen free

INTERNATIONAL HEADQUARTERS
8400.doc
MEDICAL PRODUCTS DIVISION
All Mail to: P.O. BOX 3194, Culver City, California 90231-3194
Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1178 Bank: City National Bank
e-mail: exelmed@exelmed.com

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

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KIKL'S A.V. FISTULA BIOMEQUE's A.V. FISTULA

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

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ATTACHMENT 1 (1/2)

[illegible] AV [illegible] SPECIFICATION

APPEARANCE AND WEIGHT

1. 18GX 1 1/4" cannula length : 360+/ 20mm
2. 18G X 1" cannula length : 360+/ 20mm
3. 18G X 1 1/4" cannula weight : 6.7+/ 1g
4. 18GX 1" cannula weight : 6.7+/ 1g
5. Gap between connectors and tubes must not exceed 0.3mm

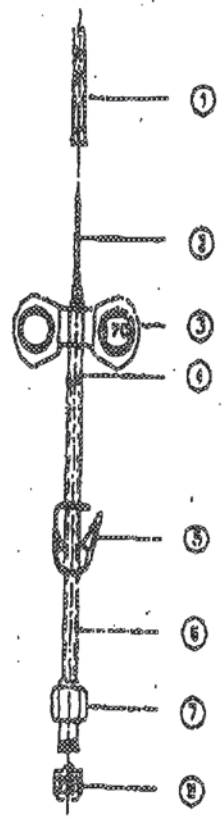
MODELS SPECIFICATION

BT-110 □□□□-□□

- Artwork in numerical order
- C: Chinese ,E: English
- R: rotating wing
- B: with back eye
- A: 48mm cannula
- 18 G cannula

NOMENCLATURE

1. Protection cap
2. Needle
3. Yellow wings
4. Needle hub
5. Small clamp
6. PVC tube
7. Female luer lock
8. Luer lock cover



PHYSICAL TESTS

CNS K6139
BIOTEQUE STANDARDS
SIYOWA JUNE 20,98. No.494

CHEMICAL TESTS

SIYOWA JUNE 28,98 No. 494

BIOLOGICAL TESTS

1. Cytotoxicity : ISO 10993-5 92'
2. Sensitization : ISO 10993-10 95'
3. Acute Intracutaneous Reaction : ISO 10993-10 95'
4. Acute Systemic Toxicity: ISO 10993-11 93'
5. Pyrogen study : USP XXIII, 95'
6. Hemolysis : ISO 10993-4 93'

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

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ATTACHMENT 2

PHYSICAL TESTS SPECIFICATION

AIR TIGHTNESS:	No leakage than 2.5 kg/cm²
PULL-OUT STRENGTH:	Over 1.4 kgf/mm²
AGING TEST:	Perform all test after 70 ℃, 24hrs
WINTER HARDY:	Perform all test after -10 ℃, 6hrs

STICKING STRENGTH: Over 0.05kgf/mm BIOTEQUE STANDARD

◆ The standard of static tensile force of connections between components as follows:

1. WING – FIXED TYPE

Parts (2) &(4) stress strength over 3.0 kg Parts (3) & (4) stress strength over 5.5 kg
Parts (4) & (6) stress strength over 4.5 kg Parts (6)&(7) stress strength over 7.0 kg

2. WING – ROTATING TYPE

Parts (2) & (4) stress strength over 3.0 kg Parts (4) &(6) stress strength over 4.5 kg
Parts (6) & (7) stress strength over 7.0 kg

◆ STAINLESS CANNULA LENGTH : 1) 15Gx 1" = 1.8x1.6x25mm
2) 15Gx 1 1/4" = 1.8x1.6x32 mm

◆ CURVATURE OF CANNULA : Should not exceed 0.031 mm

◆ STAIN COVERS SURFACE AREA : Should not exceed 0.3 mm²

◆ BURRS : Should not exceed 0.1 mm²

Product: A.V. FISTULA NEEDLE SET 60

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

(b)(4) specifications Records processed under FOIA Request 2014-7435; Released 10/23/14

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

(b)(4) Third Party Test Data Records processed under FOIA Request 2014-7435; Released 10/23/14

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

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data Records processed under FOIA Request 2014-7435; Released 10/23/14

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

(b)(4) Third Party Test Data Records processed under FOIA Request 2014-7435; Released 10/23/14

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(b)(4) Third Party Test Data Records processed under FOIA Request 2014-7435; Released 10/23/14

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

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data Records processed under FOIA Request 2014-7435; Released 10/23/14

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

(b)(4) Third Party Test Data Records processed under FOIA Request 2014-7435; Released 10/23/14

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

(b)(4) Third Party Test Data Records processed under FOIA Request 2014-7435; Released 10/23/14

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

(b)(4) Third Party Test Data Records processed under FOIA Request 2014-7435; Released 10/23/14

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

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

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data Records processed under FOIA Request 2014-7435; Released 10/23/14

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

EXEL®
INTERNATIONAL CO.

TÜV

FACSIMILE MESSAGE

DATE: 10/23/01

TO: U.S. FOOD & DRUG ADMINISTRATION
ATTN.: MS. BARBARA McCOOL

FROM: ARMAND HAMID PAGE: 1/1

RE: 510(K) No.: K013037
EXEL A.V. FISTULA NEEDLE

DEAR MS. McCOOL,

IT WAS PLEASURE SPEAKING WITH YOU.

WITH THIS LETTER I ACKNOWLEDGE OUR DISCUSSION THIS AFTERNOON.

PERTINENT TO THIS 510K, PLEASE BE KIND NOT TO FAIL SCREEN THIS APPLICATION AND PLEASE BE KIND TO PUT ON TELEPHONE HOLD SO THAT WE CAN GET REQUESTED INFORMATION FROM FACTORY AND SUBMIT TO YOU.
I WILL BE SUBMITTING THIS INFORMATION TO YOU WITHIN THIS WEEK.

BY THE WAY, YOU HAVE ASKED ME ABOUT THE FOLLOWING, WHICH I CAN GIVE THIS INFORMATION TO YOU AT THIS TIME, SINCE I HAVE THE MATERIAL AVAILABLE IN MY POSSESSION.

COMPONENTS	MATERIAL
PROTECTOR CAP FOR THE NEEDLE	POLYPROPYLENE
NEEDLE CANNULA	STAINLESS STEEL (b)(4)
HUB WING	POLYVINYL-CHLORIDE
TUBING	POLYVINYL-CHLORIDE
LUER CONNECTOR	POLYCARBONATE
LUER CAP	POLYPROPYLENE

AS INDICATED, WE ARE PREPARING THE OTHER MATERIAL AND WILL SUBMIT TO YOUR ATTENTION IMMEDIATELY.

AGAIN THANKING YOU IN ADVANCE FOR YOUR KIND ATTENTION AND HELP.

PLEASE BE KIND TO CONFIRM RECEIPT OF THIS LETTER AND CONFIRMATION OF THE CONTENT.

BEST REGARDS,

ARMAND HAMID

AH/te

INTERNATIONAL HEADQUARTERS
K013037
MEDICAL PRODUCTS DIVISION
All Mail to: P.O. BOX 3194, Culver City, California 90231-3194
Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1178 Bank: City National Bank
e-mail: exelmed@exelmed.com

COVER LTR TO FDA FOR AVF
10/23/01 4:21 PM

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

Screening Checklist
For all Premarket Notification 510(k) Submissions

3-30-01

Device Name: AV Fistula needle | K 013037

Submitter (Company): Excel International

Items which should be included (circle missing & needed information)	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA		YES		NO		✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) including forms 3454 and/or 3455	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class							
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				✓		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*					NA		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals							
k) Proposed Labeling:					✓		
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					✓		
i) Labeling					[illegible]		
ii) intended use					[illegible]		
iii) physical characteristics					[illegible]		
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS*			* If no - STOP not a special	

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

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

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

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

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

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

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

Passed Screening ✓ **Yes** ____ **No** **Reviewer:** BMc Cook

Date: 9/13/01 **Concurrence by Review Branch:** C Neuland 12/7/01

To send AI - all 7ax BMc

(10/23/01)

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

Internal Administrative Form

K 013037

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

September 11, 2001

EXELINT INTL. CO.
5840 WEST CENTINELA AVE.
LOS ANGELES, CA 90045
ATTN: ARMAND HAMID

510(k) Number: K013037
Received: 10-SEP-2001
Product: EXCEL A.V FISUTAL NEEDLE 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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

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

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

Sincerely yours,

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

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

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EXEL®
INTERNATIONAL CO.

TÜV

K013037

August 31st, 2001

Food & Drug Administration
Center for Device & Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ 401)
Rockville, MD 20850

RE: 510K NOTIFICATION/REGISTRATION

This is to notify you of the intention by EXELINT International Co. to market the following device, manufactured by (b)(4) [redacted] located in (b)(4) [redacted]

1. General Information:
   a) Classification Name: EXEL A.V. Fistula Needle Set

   b) Common/Usual Name: A.V. Fistula Needle

   c) Establishment Registration Number: (b)(4) [redacted]

   d) Name of Manufacturer: (b)(4) contractor [redacted]

   e) Device Class: II

   f) Submission: New

   g) Identify Legally Marketed Device: EXEL

   h) Equivalence of Submitted Device: This device is equivalent to our exiting A.V. Fistula Needle marketed in the industry under 510k No.: K001496.

   i) Submitter Name and Address: EXELINT International Company, 5840 W. Centinela Ave, Los Angeles, CA 90045.

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II

INTERNATIONAL HEADQUARTERS
MEDICAL PRODUCTS DIVISION
All Mail to: P.O. BOX 3194, Culver City, California 90231-3194
Central Office: 5840 W. Centinela Avenue, Los Angeles, CA 90045, U.S.A.
Tel: (310) 649-0707 Fax: (310) 649-1168 Bank: City National Bank
e-mail: exelmed@exelmed.com

SK-35 182

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

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EXEL® INTERNATIONAL CO.

TÜV

2) Safety Medical Device Act:
   a) Enclosed please review Signed Statement of 510K Summary.
   b) Enclosed please review Truthful and Accuracy Statement.
   c) Enclosed please review Indication for Use Statement.

3) Proposed Labeling:
   a) Enclosed please review our proposed package insert and labeling.
   b) Statement of Intend Use: This device consist of AVF needle, which is inserted into a patient's arterial side of their access to draw blood into an extra-corporial system and back to the patient's venous side of their access via AVF needle during Hemodialysis treatments.
   c) Promotional Material: Enclosed please review our promotional literature/brochure for this device.

4) Description of device, Diagrams, Drawings: This device is composed of following parts: (also enclosed please review sample)

   Protective Cap (for the needle)
   Needle Cannula (bevel needle)
   Hub/Wing "Rotating Wing" and "Fixed Wing" models
   Tubing (12")
   Connector, Luer Lock
   Cap (for connector)
   Enclosed please find unit samples (2 pcs.) for your review.

5) Comparison Information:

   As specified this device is similar and compatible in usage, function, and composition to the existing A.V. Fistula Needle Set marketed in the Industry by EXEL (as specified earlier).

   a) Intended Use: Please review "3C"

   b) Specification d) Material e) Performance Data: Enclosed please review pertinent data

6. Biocompatibility Data: Enclosed review pertinent data

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

EXEL® INTERNATIONAL CO.

TÜV

7. Sterilization Method:

(b)(4) sterilization

[redacted]

(b)(4) sterilization

Thanks for your kind cooperation. Please feel free to contact me at (310) 649-0707, ext. 11 if there is any question or if you require additional information.

Sincerely,

Armand Hamid

Armand Hamid
EXEL International Co.

AH/te
Encl:

INTERNATIONAL HEADQUARTERS
MEDICAL PRODUCTS DIVISION
All Mail to: P.O. BOX 3194, Culver City, California 90231-3194
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Records processed under FOIA Request 2014-7435; Released 10/23/14

510(k) STATEMENT

I certify that in my capacity as Director, of EXELINT International Co., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Armand Hamid
[Signature]

ARMAND HAMID
[Printed Name]

August 31st, 2001
[Date]

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURACY STATEMENT

(AS REQUIRED BY 21 CFR 807.87(J))

I certify that, in my capacity as the director of EXELINT INTERNATIONAL CO., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Armand Hamid

Armand Hamid

August 31st, 2001

Date

_____

(Premarket Notification (510K) Number)

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

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

Records processed under FOIA Request 2014-7435; Released 10/23/14

510(k) Number (if known): _____

Device Name: EXEL A.V FISTULA NEEDLE SET

Indications For Use:

THIS DEVICE IS AN A.V. FISTULA NEEDLE SET PART OF EXTRACORPORIAL ARTIFICAL KIDNEY SYSTEM FOR THE TREATMENT OF PATIENTS WITH RENAL FAILURE TO PROVIDE ACCESS TO THE PATIENT'S BLOOD VESSEL FOR HEMODIALYSIS.

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

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Table 1: Comparison to Predicate Device

ELEMENT OF COMPARISON	HANACO A.V. FISTULA NEEDLE SET	EXEL A.V. FISTULA NEEDLE SET
1. Intended Use(S)	The Arterial-Venous Fistula (A.V.F.) Needle Set consist of *arterial fistula needle*, which applies on the access site of patient's artery to draw the blood in to extra-corporeal system and back into the patient's vein via *venous fistula needle* during hemodialysis.	This device consist of *arterial fistula needle*, which is inserted into a patient's arterial side of their access to draw blood into an extra-corporeal system and back to the patient's venous side of their access via A.V. Fistula needle during Hemodialysis.
2. Labeling	See attachment	See attachment
3. Instruction for Use	Remove protection cap Insert needle into patients vein and allow all the air to outflow Connect Fistula needle to end connector of the arteriovenous line.	Idential
4. Configuration of the Device	See attachment	Identical
5. Bio-compatibility	See attachment	Identical
6. Physical Test	See attachment 2	Identical
7. Chemical test	See attachment 3	Identical
8. Sterilization Method	(b)(4) sterilization [redacted]	(b)(4) sterilization [redacted]
9. SAL		
10. Pyrogenic	Pyrogen free Compatible to USP standards	Pyrogen free

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TYPE OF PACKAGE FOR AVF FINISH PRODUCT

NUMBERS 1 CARTON = 6 INNER BOX 1 INNER BOX = 50PCS
SPESIFICATION CARTON SIZE: 485 x 445 x 265MM

(b)(4) contractor [redacted]

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CIRCULATION TEST OF PHYSICAL FUCTION FOR SINGLE USE

LOT NO.	010211	SPECIFICATION	H-301B 16G x 1"	TEST DATE	2001.02.12
PATCH	15.000PCS	MF DATE	2001.02.10	TEST QUANTITY	5PCS

ITEM	COMPANY STANDARD REQUIREMENT	RESULT	CONCLUSION
DIMENSION	CANNULA SIZE OF AVF IS CONFIRMED TO THE REQUIREMENT OF CHART 3&2	OUTER DIMENSION:1.64MM REVEALING PART:25MM	ACCEPTABLE
EXTERIOR	AVF CANNULA SHOULD SHARP AND NO BURR, FLAT, BEND	BE UP TO THE STANDARD	ACCEPTABLE
	THE TUBE WILL BE SOFT, TRANSPARENT, BRING AND CLEAN, NO MACHINARY SPOT, DIFFERENT MATERIAL, KINK. THE TRANSPARENCY SHOULD BE GARANTEED TO FIND BUBBLE AND RETURN BLOOD.	BE UP TO THE STANDARD	ACCEPTABLE
	THERE IS NO OBVIOUS VISIBLE DIFFERENT MATERIAL FROM AVF SEAL PACKAGE.	BE UP TO THE STANDARD	ACCEPTABLE
	THE COLOR OF AVF NEEDLE SHOULD CONFIRM TO THE STIPULATION OF CHART 3	BE UP TO THE STANDARD	ACCEPTABLE
	THE SURFACE OF AVF NEEDLE SHOULD BE SMOOTH, NO OBVIOUS MANUFACTURERED DEFECTS, AND NO DIFFERENT MATERIAL INSIDE THE NEEDLE.	BE UP TO THE STANDARD	ACCEPTABLE
FIRM CONNECTION	SOME CONNECTIONS OF AVF SHOULD BE FIRM UNDER THE TEST OF 40N. IT WILL NOT LOOSE & SEPERATION.	BE UP TO THE STANDARD	ACCEPTABLE
CONFIRMAITY	CONNECTOR AND INSERTED CONE CONNECTOR SHOULD BE CLOSE. WHILE ADDING THE AXIAL POWER OF 27.5N, AT THE SAME TIME KINKING, THE STRENGTH UNDER 0.1 NM, ROTATING IS UNDER 91 , LASTING 5S, UNDER 300KPA WATER PRESSURE, KEEPING 30S, WATER DROP OUT.	BE UP TO THE STANDARD	ACCEPTABLE
SEPERATION STRENGTH	ASSEMBLING UNDER THE CLAUSE OF STIPUTION OF 4.6.1, ADD 15N AXIAL POWER AGAINST THE DIMENTION OF TESTING CONE CONJUCTION AND CONNECTOR SHOUD NOT BE SEPERATED.	BE UP TO THE STANDARD	ACCEPTABLE

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ITEM	COMPANY STANDARD REQUIREMENT	RESULT	CONCLUSION
LEAKAGE TESTING	UNDER 100KPA OF AIR PRESSURE IN THE TUBE OF AVF. THERE IS NO LEAK WHILE KEEPING 10MM.	NO LEAK	ACCEPTABLE
FLOW VOLUME	WHEN 0.1KG OF PRESSURE IN AVF NEEDLE, THE FLOW VOLUME OF DISTILLED WATER SHOULD BE HIGHER THAN THE VOLUME ON CHART 4.	FLOW VOLUME:220ML/MIN (STANDARD:190ML/MIN)	ACCEPTABLE
CLAMP	WHILE CLOSE CLAMP. THE FLOW WILL STOP AND LOOSE IT. THE FLOW WILL BE SMOOTH.	BE UP TO THE STANDARD	ACCEPTABLE
INDIVIDUAL PACKAGE	FACTORY NAME. MARK & ADDRESS	HAVE	ACCEPTABLE
	COMMDODITY. SPECIFICATION & STOCK METHOD	HAVE	ACCEPTABLE
	STERILIZATION BY EOG	HAVE	ACCEPTABLE
	NON-TOXIC. NON-BACTRIUM, NON-PYROGEN	HAVE	ACCEPTABLE
	MODEL & LOT NO.	HAVE	ACCEPTABLE
	EXPIRATION	HAVE	ACCEPTABLE
OTHERS	SHOULD CONFIRM TO THE STIPULATION OF 2BC 48006	BE UP TO THE STANDARD	ACCEPTABLE

INSPECTOR: XIAOQIAN LI

CONFIRMED BY: KUN ZHANG

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(b)(4) design specification

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ATTACHMENT 1

EXEL®

ET.O. STERILIZED PYROGEN FREE

ARTERIAL VENOUS FISTULA NEEDLE

TUBE:
I.D. 0.14" Length 12"
Capacity 0.1 OZ

EXELINT INTERNATIONAL, CO.
5840 W.CENTINELA AVENUE, LOS ANGELES, CA 90045
TEL. : (310) 649-0707 FAX : (310) 649-1178

EXEL® Made in Thailand

DIRECTIONS FOR USE

CAUTION

50 PCS

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HANACO® A.V.FISTULA NEEDLE SET 动静脉穿刺针

STERILE EO ②

无菌、无毒、无热源。

- FOR SINGLE USE.Discard after use.
- Do not use if package is opened or damaged.
- Do not store at extreme temperature and humidity.

国药管械(准)字98第315005号

(2000) 津医卫许字第0321号

- 一次性使用，用后销毁
- 包装破损，请勿使用

- Remove protection cap.
- Insert needle into patients vein and allow all the air to outflow.
- Connect fistula needle to end connector of the arteriovenous line.

天津哈娜好医材有限公司

天津经济技术开发区洞庭路129号 66201536

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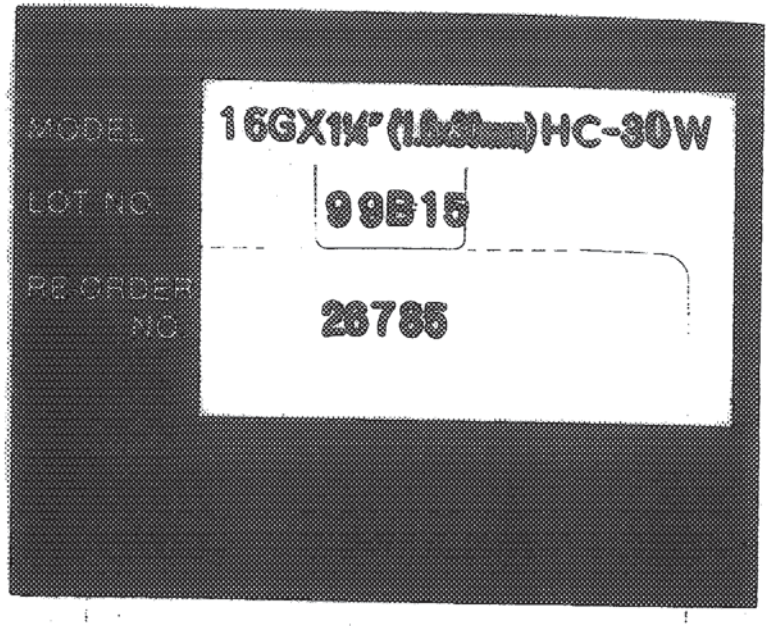
ATTACHMENT 2



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