SAVE REQUEST

USER: (ldt)
FOLDER: K030974 - 93 pages
COMPANY: BAXTER HEALTHCARE CORP. (BAXTHEAL)
PRODUCT: DIALYZER, HIGH PERMEABILITY WITH OR WITHOUT SEALED DIALYSATE SYSTEM (KDI)
SUMMARY: Product: EXELTRA HIGH FLUX DIALYZER, MODELS 150 & 170

DATE REQUESTED: Oct 8, 2014
DATE PRINTED: Oct 8, 2014

Note: Printed
510(K) SUMMARY

Submitter's Name: David E. Curtin, RAC

Address: 1620 Waukegan Rd. MPGR-A2E

Phone: (847) 473-6079

Fax: (847) 473-6952

Contact: David E. Curtin

Date Prepared: 3/27/03

Trade Name: EXELTRA™ Dialyzer, Single Use

Common Name: Dialyzer

Classification Name: High Permeability Hemodialysis System per 21 CFR 876.5860

Equivalent Predicate: Baxter CT Dialyzer, Single Use (K890315, K926568, K970663)

Device Description: Model EXELTRA™ 150 and 170 Single Use Dialyzers

Intended Use: Hemodialysis with EXELTRA™ dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

Summary of the Technological Characteristics Compared to the

The general design and material of the EXELTRA™ 150 and 170 single use dialyzers are similar to the CT 110 and CT190G dialyzers cleared under K890315, K926568 and K970663, and do not raise any new types of safety and effectiveness issues, when compared to the predicate product.
Predicate Device: Baxter CT Dialyzers

Clinical Data: N/A

Conclusions Drawn
Components of the subject EXELTRA™ dialyzers have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical devices – Part: Guidance on selection of tests.

The validation of the gamma sterilization cycle for the EXELTRA™ dialyzer is based upon the AAMI/ISO 11137:1994 “Sterilization of Healthcare Products – Requirements for Validation and Routine Control – Radiation Sterilization”.

Functional testing for blood side integrity and conformance to manufacturing specifications are performed as in-process and/or final inspections prior to product release to ensure a quality product.

Additional Information
Requested by FDA: None to date
Dear Mr. Curtin:

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.
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:

<table>
<thead>
<tr>
<th>Regulation Number</th>
<th>Phone Numbers</th>
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<tr>
<td>8xx.1xxx</td>
<td>(301) 594-4591</td>
</tr>
<tr>
<td>876.2xxx, 3xxx, 4xxx, 5xxx</td>
<td>(301) 594-4616</td>
</tr>
<tr>
<td>884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx</td>
<td>(301) 594-4616</td>
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<tr>
<td>892.2xxx, 3xxx, 4xxx, 5xxx</td>
<td>(301) 594-4654</td>
</tr>
<tr>
<td>Other</td>
<td>(301) 594-4692</td>
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</table>

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](http://www.fda.gov/cdrh/dsma/dsmamain.html).

Sincerely yours,

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

Enclosure
Indications for Use Statement

510(k) Number (if known): K030974

Device Name: EXELTRA™ Dialyzer

Indications For Use:

Hemodialysis with the EXELTRA™ Dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH/Office of Device Evaluation (ODE)

Division Sign-Off
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K030974

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)
Re: Please see enclosed list

Dear Mr. Seidman:

We have reviewed your letter, dated October 31, 2012, stating that you have changed your address and/or contact information for the above referenced premarket notifications (510(k)s). Consequently, we cannot change the original address of the 510(k) submitter in our database. It will remain as it was listed when the final decision was rendered on your 510(k)s. We suggest that you update your address through the Establishment Registration website http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm. You may contact the Center for Devices and Radiological Health's Office of Compliance at (301) 796-5500 if you have any questions regarding your change of address.

If you have any other questions regarding this letter, please contact the 510(k) Staff at (301) 796-5640.

Sincerely yours,

Marjorie Shulman
Director, Premarket Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Date: 11/5/12

From: DMC (HFZ-40)

Subject: Premarket Notification Number(s): K030974/A001

To: Division Director:

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; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

- No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

**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: ________________________________

Date: ________________________________
October 31, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Attn: Division of Reproductive, Gastro-Renal and Urological Devices

Re: Change of Official Correspondent
Change of Address of Official Correspondent
For the attached list of 510(k) Premarket Notifications

Dear Colleague:

This letter is to advise you of the change to the Official Correspondent and the change of address for the Official Correspondent for the 510(k) Premarket Notifications listed in the attached table. Effective immediately, please address all official correspondence to:

Jesse Seidman
Director, Global Regulatory Affairs
Medical Products - Renal
Baxter Healthcare Corporation
32650 N. Wilson Road, WG2-3S
Round Lake, IL 60073
Telephone: 224.270.4412
Fax: 224.270.4119

Thank you for making this change to our files. Please contact me at 224.270.4412 or via email at jesse_seidman@baxter.com with any questions regarding this request.

Sincerely,

Jesse K. Seidman, MS, RAC
Director, Global Regulatory Affairs
Baxter Healthcare Corporation
## List of 510(k)s Effected by Correspondent / Address Change

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<th>510(k) NUMBER</th>
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<th>CLEARANCE DATE</th>
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<td>K912839</td>
<td>LAPAROOPTX(TM) INTRAOPER DEFLECT CHOLEDOCHOSCOPE</td>
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**List of 510(k)s Effected by Correspondent / Address Change**

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<tr>
<td>K911106</td>
<td>MODEL BAXTER ULTRAFILTRATE METER AND DRAIN BAG</td>
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<td>K910270</td>
<td>PREMIXED DIALYSATE FOR HEMODIAFILTRATION</td>
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<td>BAXTER LAPAROSCOPIC CHOLANGIOGRAPHY CATHETERS</td>
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<tr>
<td>K905228</td>
<td>MODEL CA.150 CELLULOSE ACETATE HOLLOW FIBER DIALYZ</td>
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<td>K904734</td>
<td>PHARMASEAL DISPOSABLE ABDOMINAL TROCAR</td>
<td>11/21/1990</td>
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<td>CAPD DISPOSABLE DISCONNECT Y-SET CODE: 5C4481</td>
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<td>K901038</td>
<td>SPS 550-IPS (INTEGRATED PATIENT STATION)</td>
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<tr>
<td>K900086</td>
<td>HEMORRHOIDAL LIGATOR WITH SUCTION</td>
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<td>ARTERIOVENOUS FISTULA SETS</td>
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<td>CAPD ULTRAVIOLET(U.V.) GERMICIDAL EXCHANGE DEV SYS</td>
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<td>ANGIOSCOPE W/INTEGRATED IRRIGATING CHANNEL</td>
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<td>K881781</td>
<td>CATHETER STRAP</td>
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<td>ALTERNATE BLOOD PORT DESIGN FOR ADDIT. MEMB. OF CA</td>
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<td>K830021</td>
<td>AVF NEEDLE</td>
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<td>K760717</td>
<td>FLEXIBLE BIOPSY FORCEPS</td>
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<td>K760069</td>
<td>BAG LEG URINE COLLECTING DEVICE</td>
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<td>K760178</td>
<td>ELECTRODE CUTTING LOOP</td>
<td>10/15/1976</td>
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<td>K760716</td>
<td>FLEXIBLE FOREIGN BODY FORCEPS</td>
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<td>ADAPTER RESECTOSCOPE</td>
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<td>K760176</td>
<td>FLOORSTAND FIBER OPTIC LIGHT SOURCE</td>
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<td>K760177</td>
<td>TELESCOPE RIGID ENDOSCOPE</td>
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<tr>
<td>K760274</td>
<td>TIP RUBBER PERFORATED</td>
<td>8/30/1976</td>
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</table>
Dear Mr. Curtin:

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
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:

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Number</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>8xx.1xxx</td>
<td></td>
<td>(301) 594-4591</td>
</tr>
<tr>
<td>876.2xxx, 3xxx, 4xxx, 5xxx</td>
<td></td>
<td>(301) 594-4616</td>
</tr>
<tr>
<td>884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx</td>
<td></td>
<td>(301) 594-4616</td>
</tr>
<tr>
<td>892.2xxx, 3xxx, 4xxx, 5xxx</td>
<td></td>
<td>(301) 594-4654</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>(301) 594-4692</td>
</tr>
</tbody>
</table>

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
Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if known): K030974

Device Name: EXELTRA™ Dialyzer

Indications For Use:

Hemodialysis with the EXELTRA™ Dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.
March 28, 2003

BAXTER HEALTHCARE CORP.
RENAL DIVISION
1620 WAUKEGAN Rd., MPR-D1
MCGAWS PARK, IL 60085
ATTN: DAVID E. CURTIN

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/cdrh/mdufma).

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 one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/cde/a02-01.html.

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, 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
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health
SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(K)] SUBMISSIONS

510(k) Number: _______________

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- [ ] Special 510(k) - Do Sections 1 and 2
- [ ] Abbreviated 510(k) - Do Sections 1, 3 and 4
- [ ] Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

<table>
<thead>
<tr>
<th>Element</th>
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<th>Inadequate or Missing</th>
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</thead>
<tbody>
<tr>
<td>Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Table of Contents.</td>
<td>x</td>
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</tr>
<tr>
<td>Truthful and Accurate Statement</td>
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<tr>
<td>Device’s Trade Name, Device’s Classification Name and Establishment Registration Number.</td>
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<tr>
<td>Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).</td>
<td>x</td>
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<tr>
<td>Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.</td>
<td>x</td>
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<tr>
<td>Statement of Indications for Use that is on a separate page in the premarket submission.</td>
<td>x</td>
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<tr>
<td>Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.</td>
<td>x</td>
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<tr>
<td>510(k) Summary or 510 (k) Statement.</td>
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<tr>
<td>Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.</td>
<td>x</td>
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<tr>
<td>Identification of legally marketed predicate device. *</td>
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<tr>
<td>Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]</td>
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<tr>
<td>Class III Certification and Summary. **</td>
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<tr>
<td>Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]</td>
<td>N/A</td>
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<td>510(k) Kit Certification. ***</td>
<td>N/A</td>
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* - May not be applicable for Special 510(k) s.
** - Required for Class III devices, only.
### Section 2: Required Elements for a SPECIAL 510(k) submission:

<table>
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<th>Element</th>
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<tr>
<td>Name and 510(k) number of the sponsor’s own, unmodified predicate device.</td>
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<td>☐</td>
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<tr>
<td>A description of the modified device and a comparison to the sponsor’s predicate device.</td>
<td>☒</td>
<td>☐</td>
</tr>
<tr>
<td>A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor’s unmodified predicate device</td>
<td>☒</td>
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<tr>
<td>A statement that the modification has not altered the fundamental technology of the sponsor’s predicate device.</td>
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<td>☐</td>
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<tr>
<td>A Design Control Activities Summary that includes the following elements (a-c):</td>
<td></td>
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</tr>
<tr>
<td>a. 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.</td>
<td>☒</td>
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</tr>
<tr>
<td>b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.</td>
<td>☒</td>
<td>☐</td>
</tr>
<tr>
<td>c. A Declaration of Conformity with design controls that includes the following statements:</td>
<td>☒</td>
<td>☐</td>
</tr>
<tr>
<td>A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.</td>
<td>☒</td>
<td>☐</td>
</tr>
<tr>
<td>A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.</td>
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Section 3: Required Elements for an ABBREVIATED 510(k)*submission:

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<th>Inadequate or Missing</th>
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<tr>
<td>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. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)</td>
<td></td>
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</tr>
<tr>
<td>For submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]</td>
<td></td>
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<tr>
<td>For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.</td>
<td></td>
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<tr>
<td>For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For a submission, which relies on a non-recognized standard that has not been historically accepted by the FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.</td>
<td></td>
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</table>

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.
Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

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<th>Requirement</th>
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<td>a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:</td>
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<tr>
<td>b) Sterilization and expiration dating information:</td>
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<tr>
<td>i.) sterilization process</td>
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</tr>
<tr>
<td>ii.) validation method of sterilization process</td>
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<tr>
<td>iii.) SAL</td>
<td></td>
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<tr>
<td>iv.) packaging</td>
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<tr>
<td>v.) specify pyrogen free</td>
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<tr>
<td>vi.) ETO residues</td>
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<td>vii.) radiation dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Software Documentation:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Items with checks in the “Present but Deficient” column require additional information from the sponsor. Items with checks in the “Missing” column must be submitted before substantive review of the document.

Passed Screening  □ Yes  □ No

Reviewer:_____________________________________________________

Concurrence by Review Branch:__________________________

Date:__________________________

The deficiencies identified above represent the issues we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at:  
http://www.fda.gov/cdrh/modact/leastburdensome.html
# TABLE of CONTENTS

<table>
<thead>
<tr>
<th>Screening Checklist</th>
<th>i – iv</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premarket Submission Cover Sheet</td>
<td>2</td>
</tr>
<tr>
<td>Cover Letter</td>
<td>6</td>
</tr>
<tr>
<td>510(k) Checklist</td>
<td>8</td>
</tr>
<tr>
<td>Substantial Equivalence Decision Making Process</td>
<td>13</td>
</tr>
<tr>
<td>Truthful and Accuracy Statement</td>
<td>15</td>
</tr>
<tr>
<td>510(k) Summary</td>
<td>16</td>
</tr>
<tr>
<td>Indications for Use Statement</td>
<td>18</td>
</tr>
<tr>
<td>TAB 1 Proposed Product Labeling</td>
<td>19</td>
</tr>
<tr>
<td>TAB 2 Predicate Product Labeling</td>
<td>29</td>
</tr>
<tr>
<td>TAB 3 EXELTRA Product Drawing</td>
<td>39</td>
</tr>
<tr>
<td>TAB 4 Component List and Comparison to Predicate</td>
<td>40</td>
</tr>
<tr>
<td>TAB 5 Description of Fiber Material and</td>
<td>42</td>
</tr>
<tr>
<td>Manufacturing Process</td>
<td></td>
</tr>
<tr>
<td>TAB 6 Declaration of Conformity Statement</td>
<td>44</td>
</tr>
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</table>
Date of Submission: March 27, 2003

Section A  Type of Submission

- PMA
  - Original Submission
  - Modular Submission
  - Amendment
  - Report
  - Report Amendment

- PMA Supplement
  - Regular
  - Special
  - Panel Track
  - 30-Day Supplement
  - 30-Day Notice
  - 135-Day Supplement
  - Real-Time Review
  - Amendment to PMA Supplement

- PDP
  - Pre-submission
  - Original PDP
  - Notice of Intent to Start clinical trials
  - Intention to Submit
  - Notice of Completion
  - Amendment to PDP

- 510(k)
  - Original Submission
    - Traditional
    - Special
    - Abbreviated
    - Additional Information

- Meeting
  - Pre-IDE Meeting
  - Pre-PMA Meeting
  - Pre-PDP Meeting
  - 180-Day Meeting
  - Other (Specify)

- IDE
  - Original Submission
  - Amendment
  - Supplement
  - Report

- Humanitarian Device Exemption
  - Original Submission
  - Amendment
  - Supplement
  - Report

- Class II Exemption
  - Original Submission
  - Amendment
  - Supplement
  - Report

- Evaluation of Automatic Class III Designation
  - Original Submission
  - Amendment
  - Supplement
  - Report

- Other Submissions
  - Original Submission
  - Amendment
  - Supplement
  - Report

Describe Submission:

Applicant or Sponsor

Company / Institution Name: Baxter Healthcare Corporation
Establishment Registration Number: 1417572

Division Name (if applicable): Renal Division, MPGR-A2E

Street Address: 1620 Waukegan Road
City: McGaw Park
State / Province: IL

Contact Name: David E. Curtin, RAC
Contact Title: Associate Director, Regulatory Affairs
Contact E-Mail Address: curtind@baxter.com

Submit or Correspondent (if different from above)

Company / Institution Name: Establishment Registration Number:

Division Name (if applicable): Phone Number (Include Area Code):

Street Address: FAX Number (Include Area Code):

City: State / Province: Country:

Contact Name: Contact E-Mail Address:
<table>
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<tr>
<th>Section D2</th>
<th>Reason for Submission – 510(k)</th>
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<tr>
<td>New Device</td>
<td>Change in Technology</td>
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<tr>
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<td>Change in Design</td>
</tr>
<tr>
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<td>Change in Materials</td>
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<tr>
<td>Change in Technology</td>
<td>Change in Manufacturing Process</td>
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<td>Other Reason (Specify):</td>
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Device modification adding new code consisting of different fiber count and fiber surface area.
**Section E. Additional Information on 510(k) Submissions**

<table>
<thead>
<tr>
<th>Product codes of devices to which substantial equivalence is claimed:</th>
<th>Summary of, or statement concerning safety and effectiveness data:</th>
</tr>
</thead>
</table>
| 1 78KDI 2 3 4 5 6 7 8                                               | ■ 510(k) Summary Attached  
  □ 510(k) Statement                                                   |

Information on devices to which substantial equivalence is claimed:

<table>
<thead>
<tr>
<th>510(k) Number</th>
<th>Trade or Proprietary or Model Name</th>
<th>Manufacturer</th>
</tr>
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<tr>
<td>1</td>
<td>1 Capillary Flow Dialyzer, Models</td>
<td>1 Baxter Healthcare Corporation</td>
</tr>
<tr>
<td>2</td>
<td>2 Baxter CT Dialyzer</td>
<td>2 Baxter Healthcare Corporation</td>
</tr>
<tr>
<td>3</td>
<td>3 Baxter CT Dialyzer</td>
<td>3 Baxter Healthcare Corporation</td>
</tr>
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<td>4</td>
<td>4</td>
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<tr>
<td>5</td>
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</tbody>
</table>

**Section F. Product Information – Applicable to All Applications**

Common or Usual Name or Classification Name:

High Permeability Hemodialysis System

<table>
<thead>
<tr>
<th>Trade or Proprietary or Model Name</th>
<th>Model Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exeltra™ Dialyzer, Single Use</td>
<td>1 Exeltra 150 Dialyzer</td>
</tr>
<tr>
<td>2 Exeltra™ Dialyzer, Single Use</td>
<td>2 Exeltra 170 Dialyzer</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
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</tbody>
</table>

FDA Document Numbers of All Prior Related Submissions (Regardless of Outcome):

<table>
<thead>
<tr>
<th>1 2 3 4 5 6 7 8 9 10 11 12</th>
</tr>
</thead>
</table>

Data Included in Submission:

- □ Laboratory Testing
- □ Animal Trials
- □ Human Trials
Section C  Product Classification – Applicable to All Applications

Product Code: 78K1D

Classification Panel:
Gastroenterology and Urology

Indications (From Labeling):

Hemodialysis with Exeltra™ Dialyzer is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Registration Form.

Section II  Manufacturing/ Packaging/ Sterilization Sites Relating to a Submission

Company / Institution Name: Nipro Corporation

Division Name (If Applicable): International Division

Street Address: 8-7 Hanakiyachii Nijda

City: Odate City State / Province: Akita Pref. Country: Japan

Contact Name: Mr. Nori Watanabe

Contact Title: Director International Division

Contact E-Mail Address:

Company / Institution Name: Nipro Corporation

Division Name (If Applicable): International Division

Street Address: 8-7 Hanakiyachii Nijda

City: Odate City State / Province: Akita Pref. Country: Japan

Contact Name: Mr. Nori Watanabe

Contact Title: Director International Division

Contact E-Mail Address:
March 27, 2003

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

RE: 510(k) Premarket Notification
EXELTRA™ 150 and EXELTRA™ 170 Dialyzers, Single Use

Special 510(k): Device Modification

Ladies/Gentlemen:

As required by Section 510(k) of the Medical Device Amendments of 1976, and in conformance with 21 CFR, Part 807, we are providing you with prior notice that we propose to market the EXELTRA™ 150 and EXELTRA™ 170 Dialyzers, Single Use.

The EXELTRA™ 150 and 170 Dialyzers are cellulose triacetate dialyzers and are exactly the same as the CT110G and CT190G single use dialyzers cleared under Baxter’s premarket notification applications K890315, K926568 and K970663. The only difference between the previously cleared cellulose triacetate dialyzers and the proposed dialyzers is in the amount of fibers contained within the dialyzer case. The predicate dialyzers consist of 1.1 m² of fibers (CT110G) and 1.9 m² of fibers (CT190G). The proposed dialyzer consists of 1.5 m² of fibers (EXELTRA 150) and 1.7 m² of fibers (EXELTRA 170). Additionally, we are introducing the trademark EXELTRA to identify our family of single use cellulose triacetate dialyzers. All other aspects of the proposed dialyzers are exactly the same as the predicate dialyzers including the materials of construction, manufacturing process and site, sterilization process (gamma sterilization) and packaging. The proposed dialyzers are intended for single use only.

The proposed dialyzers are substantially equivalent to the predicate dialyzers currently marketed by Baxter and cleared under K890315, K926568 and K970663. Substantial equivalence is as described in the attached tab entitled Substantial Equivalence.
Any questions regarding the preparation and content of this submission or requests for additional information may be addressed to me at the phone number listed below. In the event I am not available, please contact Mr. Robert Wilkinson at 847-473-6335.

Sincerely,

Baxter Healthcare Corporation

David E. Curtin, RAC
Associate Director, Regulatory Affairs
Renal Division
(847) 473-6079
(847) 473-6952 FAX
curtind@baxter.com
510(K) Premarket Notification Checklist
EXELTRA™ 150 and 170 Dialyzer, Single Use

Device Trade or Proprietary Name: EXELTRA™ High Flux Dialyzer

Device Common Usual Name: High Permeability Hemodialysis System

Class into which Device is Classified Under Section 513: Class II

Device Classification Name: High Permeability Hemodialysis System 21 CFR 876.5860

Classification Panel: Gastroenterology and Urology

Product Code: 78 KDI

Owner Operator Number and Address: Baxter Healthcare Corporation 1 Baxter Parkway Deerfield, IL 60015, USA

Establishment Registration Number and Manufacturing Facilities: [b] [4]

Action taken to comply with §514 of the ACT, Performance Standards or §513 Special Controls: High Permeability Hemodialysis Systems were reclassified into Class II (special controls), pursuant to a final rule published in the Federal Register Vol. 65, No. 63, March 31, 2000.

We are in compliance with the performance standards established under Section 514 of the Food, Drug and Cosmetic Act including “Biological Evaluation of Medical Devices Part I: Evaluation and Testing” per ISO 10993-1 and “Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers.”
510(k) Premarket Notification
EXELTRA™ 150 and 170 Single Use Dialyzers
Page 2

Reason for 510(k) Premarket Notification:
Device Modification. The EXELTRA™ 150 and 170 dialyzers are an addition to Baxter’s Cellulose Triacetate (CT) Dialyzer product line and represents additional fiber surface areas to the currently marketed products. The EXELTRA™ 150 and 170 dialyzers are intended for Single Use Only, and are not validated or labeled for multiple use.

Equivalence to Marketed Predicate:
The EXELTRA™ 150 and 170 single use dialyzers are substantially equivalent to the CT 110G and CT 190G dialyzers previously cleared under K890315, K926568 and K970663. The indication for use, components, materials of construction, manufacturing process, sterilization process and packaging of the EXELTRA™ 150 and 170 single use dialyzers are the same as the predicate CT 110G and CT 190G dialyzers. The trademark EXELTRA will be used to identify Baxter’s family of single use cellulose triacetate dialyzers.

The only difference between the proposed dialyzers and the predicate dialyzers is the number of fibers contained within the dialyzer case. The proposed dialyzer contains 1.5 \( m^2 \) of fibers (EXELTRA™ 150) and 1.7 \( m^2 \) of fibers (EXELTRA™ 170). The predicate dialyzers contain 1.1 \( m^2 \) of fibers (CT 110G) and 1.9 \( m^2 \) of fibers (CT 190G). The dialyzer case for the proposed dialyzers has been sized appropriately to accommodate the number of fibers.

Proposed Labeling:
Draft labeling, including Unit label Pouch Label, Carton Label, Performance Data Sheets and Directions for Use for the EXELTRA™ 150 and 170 dialyzers are provided in TAB 1.

These products are intended for distribution in the US and Canada, including territories where French is the predominant language. As such, the labeling and labels include both English and French language, the French being an exact translation of the English text.

We are pursuing Canadian regulatory approval separately.

Equivalent Device Labeling:
Copies of the labeling for the predicate CT 110G and CT 190G dialyzers are provided in TAB 2.
A product drawing of the EXELTRA™ dialyzer is provided in TAB 3.

The EXELTRA™ 150 and 170 dialyzers are cellulose triacetate dialyzer and will be labeled for single use only.

These dialyzers are exactly the same as the predicate cellulose triacetate CT 110G and CT 190G dialyzers currently cleared under K890315, K926568 and K970663.

A list of components comparing the predicate dialyzers to the proposed dialyzers is provided in TAB 4.

The indication for use, components, materials of construction, manufacturing process, sterilization process and packaging of the EXELTRA™ 150 and 170 dialyzers are the same as the predicate CT 110G and CT 190G dialyzers. A description of the fiber material and manufacturing process is provided in TAB 5.

The only difference between the proposed dialyzer and the predicate dialyzers is the number of fibers contained within the dialyzer case. The proposed dialyzers contain 1.5 m² of fibers (EXELTRA™ 150) and 1.7 m² of fibers (EXELTRA™ 170). The predicate dialyzers contain 1.1 m² of fibers (CT 110G) and 1.9 m² of fibers (CT 190G).

Hemodialysis with EXELTRA™ dialyzer is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

This intended use statement is exactly the same as the intended use statement for the predicate products, with the exception that we have added the trade name EXELTRA™ to describe this family of dialyzers.

Hemodialysis with these dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It may also be indicated in the treatment of patients intoxicated with poisons or drugs.
Summary of the Technological Characteristics and Physical Comparison to the Predicate Device:

The EXELTRA™ dialyzer is a High Flux, gamma sterilized single use product that provides 1.5 m$^2$ and 1.7 m$^2$ of fiber surface area. The EXELTRA™ dialyzer is identical to the CT dialyzer in all aspects including indication for use, components, materials of construction, manufacturing process, sterilization process and packaging. The proposed dialyzers represent the addition of new fiber surface areas. This modification does not alter the fundamental technology represented by the predicate products. A summary of the technological characteristics and physical comparison between the EXELTRA™ dialyzer and the CT dialyzers is provided in TAB 4.

Biocompatibility

The proposed dialyzers consist of the exact same materials of construction as the predicate products. As such, biocompatibility has been established via the predicate product 510(k)s K890315, K926568 and K970663.

Design Control Activities:

The risk analysis methods used to assess the impact of the modifications were a Clinical and Hazard Analysis, Failure Modes and Effects Analysis (FMEA) and a review of the product complaint database. These analyses concluded that no additional verification and validation testing for the change in fiber surface area is required. The modified hemodialyzers were performance tested for bovine blood ultrafiltration rate and clearances of urea, creatinine, phosphate, vitamin B12 and myoglobin. The data has been included in the product data sheet.

A declaration of conformity statement that all verification and validation activities were performed by the designated individuals and results met acceptance criteria, and that the manufacturing facility is in compliance with design controls is provided in TAB 6.
Sterilization remains unchanged from that which was cleared for the predicate devices under K890315, K926568 and K970663. Sterilization dose setting is based on ANSI/AAMI/ISO-11137 Method 2B. The Sterility Assurance Level is $10^{-6}$.

Packaging remains unchanged from that which was cleared for the predicate devices under K970663.

Expiration Dating
The EXELTRA™ dialyzer will be labeled with an expiration date of three years from the production date. Expiration dating of 3 years has been previously established for the predicate devices. Since the materials of construction and manufacturing process for the proposed dialyzers are exactly the same as the predicate devices, the expiration dating will remain at 3 years.

510(k) Summary of Safety and Effectiveness
Refer to the Tab titled 510(k) Summary following this Checklist

Official Correspondent:
Robert L. Wilkinson, RAC
Director, Regulatory Affairs
Renal Division

Prepared By:
David E. Curtin, RAC
Associate Director, Regulatory Affairs
Renal Division
510(k) Substantial Equivalence: Decision-Making Process for EXELTRA 150 and EXELTRA 170 Dialyzer, Single Use

New Device is Compared to Marked Device

1. Does New Device Have Same Indication Statements?
   Yes
   No
   2. Do the Differences Alter the Intended Therapeutic/Diagnostic/etc. Effect (in Deciding, May Consider Impact on Safety and Effectiveness)
      Yes
      No
      New Device Has New Intended Use

3. New Device Has Same Intended Use and May be "Substantially Equivalent"
   Yes
   No

4. Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc?
   Yes
   No
   Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?
   No
   Performance Data Required
   Yes
   Performance Data Available to Assess Equivalence

5. Could the New Characteristics Affect Safety or Effectiveness?
   Yes
   No
   New Device Has New Intended Use

6. Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?
   Yes
   No
   New Device Has New Intended Use

7. Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?
   Yes
   No
   New Device Has New Intended Use

8. Are Performance Data Available to Assess Effects of New Characteristics?
   Yes
   No
   New Device Has New Intended Use

9. Performance Data Demonstrate Equivalence?
   Yes
   No
   New Device Has New Intended Use

"Substantially Equivalent" Determination

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Baxter 510(k) Substantial Equivalence Determination

Question#

1. Does the New Device Have the Same Indications Statements?

   Yes. The Exeltra™ Dialyzer has the same indications for use as the equivalent predicate device.

3. Does the New Device Have the Same Intended Use and is the Device “Substantially Equivalent?”

   Yes. The Exeltra™ Dialyzer has the same intended use as the predicate device, which is indicated for hemodialysis in patients with renal failure when conservative therapy is judged to be inadequate. They may also be indicated in the treatment of patients intoxicated with poisons or drugs.

   Based on the intended use of the products the Exeltra™ Dialyzer is “substantially equivalent” to the predicate device.

4. Does the New Device Have the Same Technological Characteristics, eg. Design, Materials, etc.?

   Yes. The EXELTRA™ Dialyzer has the same technological characteristics as the predicate device. The EXELTRA™ dialyzer and the predicate product are designed to filter substances from the blood. The materials of the EXELTRA™ dialyzer are exactly the same as the predicate product.

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

Yes. The descriptive characteristics are precise enough to ensure equivalence. A comparison of the proposed product to the predicate product is provided in TAB 4.

Decision: Substantially Equivalent
Pursuant to 21 CFR 807.87(j), I, David E. Curtin certify, in my capacity as Associate Director, Regulatory Affairs of Baxter Healthcare Corporation, that to the best of my knowledge and belief the data and information submitted in this Premarket Notification are truthful and accurate and that no facts material to the review of the substantial equivalence of the Exeltra™ Dialyzer have been knowingly omitted from this submission.

Baxter Healthcare Corporation

[Signature]
David E. Curtin
Associate Director, Regulatory Affairs
Renal Division

Premarket Notification [510(k)] Number
# 510(K) SUMMARY

<table>
<thead>
<tr>
<th><strong>Submitter's Name:</strong></th>
<th>David E. Curtin, RAC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Address:</strong></td>
<td>1620 Waukegan Rd. MPGR-A2E</td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
<td>(847) 473-6079</td>
</tr>
<tr>
<td><strong>Fax:</strong></td>
<td>(847) 473-6952</td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
<td>David E. Curtin</td>
</tr>
<tr>
<td><strong>Date Prepared:</strong></td>
<td>3/27/03</td>
</tr>
<tr>
<td><strong>Trade Name:</strong></td>
<td>EXELTRA™ Dialyzer, Single Use</td>
</tr>
<tr>
<td><strong>Common Name:</strong></td>
<td>Dialyzer</td>
</tr>
<tr>
<td><strong>Classification Name:</strong></td>
<td>High Permeability Hemodialysis System per 21 CFR 876.5860</td>
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<tr>
<td><strong>Equivalent Predicate:</strong></td>
<td>Baxter CT Dialyzer, Single Use (K890315, K926568, K970663)</td>
</tr>
<tr>
<td><strong>Device Description:</strong></td>
<td>Model EXELTRA™ 150 and 170 Single Use Dialyzers</td>
</tr>
<tr>
<td><strong>Intended Use:</strong></td>
<td>Hemodialysis with EXELTRA™ dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.</td>
</tr>
<tr>
<td><strong>Summary of the Technological Characteristics Compared to the</strong></td>
<td>The general design and material of the EXELTRA™ 150 and 170 single use dialyzers are similar to the CT 110 and CT190G dialyzers cleared under K890315, K926568 and K970663, and do not raise any new types of safety and effectiveness issues, when compared to the predicate product.</td>
</tr>
</tbody>
</table>
510(k) Premarket Notification
EXELTRA™ 150 and 170 Single Use Dialyzers
Page 2 of 2

Predicate Device: Baxter CT Dialyzers

Clinical Data: N/A

Conclusions Drawn
Components of the subject EXELTRA™ dialyzers have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical devices – Part: Guidance on selection of tests.

The validation of the gamma sterilization cycle for the EXELTRA™ dialyzer is based upon the AAMI/ISO 11137:1994 “Sterilization of Healthcare Products – Requirements for Validation and Routine Control – Radiation Sterilization”.

Functional testing for blood side integrity and conformance to manufacturing specifications are performed as in-process and/or final inspections prior to product release to ensure a quality product.

Additional Information
Requested by FDA: None to date
Indications for Use Statement

510(k) Number (if known): __________________________

Device Name: EXELTRA™ Dialyzer

Indications For Use:

Hemodialysis with the EXELTRA™ Dialyzer is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

(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)
Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

X For Single Use Only

⚠ See Instructions For Use

Max TMP

Sterilized By Gamma Irradiation

Baxter and EXELTRA are trademarks of Baxter International Inc.

Distributed by Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in Japan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Do not use if blood port tip protectors are not in place.
Do not use if package has been previously opened or damaged.
Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.
Avoid direct exposure to sunlight and vibrations.

**Warning:** This device must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

**Caution:** Federal (USA) law restricts this device to sale by or on order of a physician.

**Baxter and EXELTRA** are trademarks of Baxter International Inc.
Baxter et EXELTRA sont des marques de commerce de Baxter International Inc.

Distributed by/Distribue par Baxter Healthcare Corporation Deerfield, IL 60015 USA
Made in Japan/Fabriqué au Japon 07-07-36-766 2003/03

![Tear Here/Déchirer ici](image)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
5M2120

Baxter

EXELTRA High Flux Dialyzer/Dialyseur EXELTRA

Model EXELTRA 170/Modèle EXELTRA 170

Do not use if blood port tip protectors are not in place.
Do not use if package has been previously opened or damaged.
Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.
Avoid direct exposure to sunlight and vibrations.

Warning: This device must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

Baxter and EXELTRA are trademarks of Baxter International Inc.

Baxter et EXELTRA sont des marques de commerce de Baxter International Inc.

Distributed by: Distribué par
Baxter Healthcare Corporation
Croughill, IL 60015 USA

Made in Japan/Fabricé au Japon
07-07-35-152 2003/03

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

Directions for Use

Baxter cannot warrant the sterility, nonpyrogenicity, mechanical integrity or performance of this dialyzer when reused. Deviation from described method should be undertaken only under the supervision or with the approval of a physician. See specific data sheet for performance characteristics.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

Caution for Storage
Store at 0°C to 40°C, avoiding direct exposure to sunlight and vibrations.
Avoid excessive changes in relative humidity.

Indications
Hemodialysis with EXELTRA dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It may also be indicated in the treatment of patients intoxicated with poisons or drugs.
The device should be used only on the direction of a physician.

Contraindications
There are no special contraindications for use of this dialyzer for the hemodialysis procedure. Patients with a history of allergic reactions to Cellulose Triacetate should not be treated using this product.

Adverse Reactions
Patients may experience hypersensitivity (allergic) reactions during treatment. Symptoms and signs include asthmatic reactions, respiratory arrest, pruriitus, urticaria, erythema, peripheral and facial edema, hypertension, hypotension, and cardiac arrhythmia. A history of allergic responses, including asthma is an indication for careful monitoring for such signs or symptoms during treatment.

Effects such as hypotension, hypertension, headache and nausea, which may be associated with hypovolemia or hypervolemia, can usually be avoided by careful management of the patient’s fluid, electrolyte balance, blood flow rate and ultrafiltration rate.

Warnings and Precautions
Refer to specific procedure for additional warnings and precautions.

WARNING: The performance properties of reused EXELTRA dialyzers have not been established and processes for disinfectant procedures have not been validated. Ineffective removal of residual disinfectant may lead to adverse patient reactions.

Air Embolism
Air in the extracorporeal circuit during treatment must be avoided. If air gets into the system, the treatment must be discontinued and the blood must not be returned to the patient.

Hypersensitivity Reactions
It is recommended that treatment be discontinued in any patient exhibiting signs or symptoms of a hypersensitivity reaction. The blood contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient.

High Permeability Dialyzers
EXELTRA dialyzers must be used only in conjunction with dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

Use of the EXELTRA dialyzer under clinical conditions of high transmembrane pressure may result in net ultrafiltration rates that greatly exceed the ultrafiltration requirements of some patients. Under these conditions, the use of sterile reinfusion fluid is mandatory.

Diaphysate Fluid
Use of an in-line conductivity monitor is recommended. To avoid hemolysis, dialysate temperature should never exceed 42°C (107.6°F).

Treatment Procedure
1. Aseptic technique must be employed.
2. All connections should be checked carefully before and during treatment.
3. The inlet (arterial) and outlet (venous) air bubble traps must be 3/4 full at all times. Since air may be drawn into the extracorporeal circuit on the negative pressure side of the blood pump, the use of an air bubble detector on the venous line is recommended.
4. To preserve fiber integrity, do not exceed 500 mmHg (56 kPa) transmembrane pressure.
5. Weighing the patient before and after treatment is recommended to verify the extent of ultrafiltration.
6. Many dialysis products available from other manufacturers are used with equipment or disposables from Baxter Healthcare Corporation. Baxter has no control over variability, tolerances, mechanical strength or changes in these products which may be made from time to time. Therefore, Baxter cannot ensure that the dialysis products of other manufacturers, when connected with its products, will function in a satisfactory manner.
7. If the patient is under drug therapy, blood levels must be monitored to assure appropriate therapeutic levels are maintained.

Set Up Procedure
Refer to Warnings and Precautions section for additional statements.
Do not use if blood port tip protectors are not in place.
Do not use if package has been previously opened or damaged.

Initial Assembly
Connect the inlet (arterial) set, outlet (venous) set, monitoring lines, saline administration line, and heparin line (where applicable) to the dialysis machine and dialyzer.

Air Testing
Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, air leak testing before use, constant monitoring by a blood leak detector on the dialysate fluid line, and visual inspection of the system is recommended.

1. Air testing should be completed prior to wetting either the blood or dialysate sides of the dialyzer.
2. Clamp the outlet (venous) set below the bubble trap and any other tees necessary to create a closed system on the venous side.
3. Prior to turning on the blood pump, make sure there is an open port through which air can be drawn into the inlet (arterial) set through a bacterial barrier such as a sterile pressure transducer isolator. Turn on the blood pump and slowly increase the pressure in the extracorporeal circuit to 300 mmHg (39.9 kPa) as measured on the venous pressure monitor.
4. Turn off the blood pump and clamp off the inlet (arterial) set between the pump and the dialyzer.
5. If a pressure drop greater than 10 mmHg within 30 seconds occurs, check for a faulty clamp or connection before assuming a dialyzer leak exists. A confirmed drop in pressure greater than 10 mmHg within 30 seconds is not acceptable and the dialyzer should be replaced.
Priming

Adherence to rinsing instructions is essential for removal of air and residues within the device.

1. Position the dialyzer in the holder with the venous blood port directed upwards. Note: It is important to keep the dialyzer in this position during priming of the blood compartment. Close or plug both dialysate ports using the blood port tip protectors. (Refer to Figure 1)

2. Attach an IV Administration Set to a one liter container of sterile isotonic saline (0.9% saline) and connect it as follows:
   a. In a set equipped with a saline administration port, the isotonic saline can be introduced by gravity flow at the saline administration port. When the section between the port and cannula connector is free of air, cross-clamp near the cannula connector.
   b. When using a set equipped with an inlet priming port with cap over the patient connection, attach the administration set directly into the port.

3. Run the isotonic saline through the extracorporeal circuit at a flow rate of approximately 200 mL/min.

4. After approximately 500 mL of isotonic saline has been run through the dialyzer, and the dialyzer has been purged of all air, stop the blood pump and rotate the dialyzer 180 degrees so the arterial blood port (red) is directed upwards.

5. Remove tip protectors from the dialysate ports. Attach the dialysate connectors so that the dialysate fluid inlet line is near the venous blood port. Blood and dialysate fluid should flow countercurrently. Start the blood pump and initiate dialysate flow at a rate of approximately 500 mL/min. Set the ultrafiltration rate as low as possible. Do not allow the dialysate-side pressure to become greater than the blood-side pressure. Do not run the saline bag empty to prevent air from entering the system.

6. Turn off the blood pump after the extracorporeal circuit has been rinsed with 1000 mL of sterile isotonic saline. Make sure the blood compartment is filled with isotonic saline.

7. Continue to run dialysate for another 5 minutes, then proceed to clamp the arterial and venous lines near the cannula connector. Discard the spent priming fluid. The venous bubble trap should be 3/4 full.

Caution: When the priming procedure has been completed, and the extracorporeal circuit is free of air, set the ultrafiltration rate as low as possible. Do not allow the dialysate-side pressure to become greater than the blood-side pressure. This will minimize the ultrafiltration of priming solution from the dialyzer between the time when the circuit is primed and treatment is to commence. If for any reason the treatment procedure is not started immediately following the completion of priming, the isotonic saline solution in the circuit should be replaced with fresh solution immediately prior to the initiation of treatment.

Treatment Procedure

Refer to the Warnings and Precautions section for additional statements. Specific directions should be given by the attending physician.

Caution: Operation of the dialyzer at a zero net UF rate or at extremely low net UF rates may cause the dialysate-side pressure to exceed the blood-side pressure in a portion of the dialyzer. Because the likelihood of reverse UF of nonsterile dialysate into the blood is increased under these conditions, the UF rate must be carefully adjusted as directed by a physician.

Administration of Heparin

Systemic or regionalized heparinization may need to be administered based on instructions from attending physician.

Initiation of Treatment

For extracorporeal circuit configuration, refer to Figure 2.

Warning: Carefully observe the outlet (venous) bubble trap chamber as blood enters. If blood appears hemolized, clamp off the outlet (venous) set and simultaneously shut off the blood pump. Clamp off the inlet (arterial) set. Verify that the dialysate mixture is proportioned correctly and properly formulated, then explore other causes (e.g. dialysate over-temperature, improper priming fluids). Purge all incompatible fluid from the dialyzing fluid path. The blood must not be returned to the patient. When cause has been determined and corrected, discard the dialyzer and sets. Set up a new dialyzer and sets and prepare the circuit in the normal way for starting treatment.

1. Connect the arterial cannula to the inlet (arterial) set and the venous cannula to the outlet (venous) set. Secure fittings before proceeding.

2. Remove the clamps from the patient’s cannula or fistula needles and the inlet (arterial) set, then remove the outlet (venous) set clamp. Coordinate the starting of the blood pump with this action. Start the blood pump slowly and adjust the speed to at least 80 mL/min. Do not allow the level in the arterial and venous bubble traps to drop below the manufacturer’s recommended full level.

3. Check to make sure there is no air present in the arterial or venous headers. If air is present, run blood at a flow rate of 200 mL/min for five to ten minutes through the dialyzer to remove any air bubbles.

4. Ensure that the appropriate treatment parameters are properly set, e.g. blood flow rate, dialysate flow rate, ultrafiltration rate.

Treatment Monitoring

It is recommended to monitor the post-pump inlet (arterial) pressures during treatment. A continuing rise in inlet arterial pressure may indicate an obstruction in the dialyzer or lines leading to the patient.

Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, constant monitoring by a blood leak detector on the dialysate fluid line and visual inspection of the system is recommended.

If a blood leak occurs, an attempt may be made (at the discretion of the attending physician) to return blood from the extracorporeal system to the patient (see Termination of Treatment). If the decision is made not to return the blood to the patient, clamp off the outlet (venous) set and simultaneously shut off the blood pump. Clamp off the inlet (arterial) set. Discard the dialyzer and sets.

Termination of Treatment

Warning: Any air that was trapped inadvertently in the dialyzer during priming and treatment may be dislodged. Carefully monitor the level of the venous bubble trap at all times. Air rinsing of blood at the termination of treatment is not recommended.

1. Set ultrafiltration rate as low as possible. Do not allow the dialysate-side pressure to become greater than the blood-side pressure.

2. Stop dialysate flow.

3. Reduce blood pump speed to zero and sequentially clamp outlet (venous) and inlet (arterial) sets and arterial cannula.

4. Separate the inlet (arterial) set from the arterial cannula and connect the (arterial) set to a source of sterile isotonic saline.

5. Open the clamp on the fluid administration set, the inlet (arterial) set, and turn up the blood pump slowly to 100 mL/min to return the blood to the patient.

6. Intermittently clamp and unclamp the tubing beneath the venous bubble trap with a line clamp. This will increase and decrease the pressure within the dialyzer which will help reduce the amount of blood retained in the dialyzer. Do not exceed the dialysis machine pressure limits.

7. Pump the fluid through the blood tubing until the fluid in the outlet (venous) set is as clear as desired.

8. Shut off the blood pump and clamp off the outlet (venous) set and the venous cannula. Separate the outlet (venous) set from the venous cannula.

9. Discard dialyzer and all other disposable equipment. Clean dialyzing equipment following manufacturer’s instruction manual.

10. Provide appropriate care to the patient’s vascular access as prescribed by the physician.
Blood path is sterile and nonpyrogenic. Sterilized by gamma irradiation.

To preserve fiber integrity, do not exceed 500 mmHg (66 kPa) transmembrane pressure.

For single use only.

**Figure 1** - Dialyzer Orientation During Blood Compartment Priming.

**Figure 2** - Extracorporeal Circuit for Hemodialysis Treatment.

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Dialyseurs EXELTRA
Mode d’emploi

Baxter ne peut garantir la stérilité, l’appréciation de l’intégrité mécanique ou la performance du dialyseur si ce dernier a déjà été utilisé. Les modifications par rapport à la méthode indiquée doivent être effectuées seulement sous le contrôle ou avec l’accord d’un médecin. Consultez la fiche technique spécifique pour les performances.

Attention : En vertu de la loi fédérale américaine, cet appareil ne peut être vendu que par un médecin ou sur la demande d’un médecin.

Précautions de stockage
Stocker à une température de 0 °C à 40 °C, éviter les vibrations et l’exposition directe au soleil. Éviter les variations excessives d’humidité relative.

Indications
L’utilisation du dialyseur EXELTRA est indiquée pour l’hémodialyse chez les patients souffrant d’insuffisance rénale pour lesquels le traitement classique est jugé inadéquat, ou en cas d’intoxication médicamenteuse due à l’ingestion de médicament ou de poison.

Ce dispositif ne doit être utilisé que sous la stricte surveillance d’un médecin.

Contre-indications
Il n’existe aucune contre-indication spécifique en rapport avec l’utilisation de ce dialyseur lors d’une procédure d’hémodialyse. Chez les patients présentant des antécédents de réaction allergique au triacétate de cellulose ne doivent pas être dialysés avec ce produit.

Effets indésirables
Des réactions d’hypersensibilité (type allergique) peuvent se présenter durant le traitement. Des symptômes et des signes de réactions asthmatiques, d’arrêt respiratoire, de prurit, d’utilicurie, d’érythème, d’anémie périphérique et facial, d’hypertension, “hypotension”, et d’arythmie cardiaque ont été signalés. Chez les patients présentant des antécédents de réactions allergiques, y compris l’asthme, il est nécessaire de surveiller les signes et les symptômes pendant le traitement.

Les effets secondaires souvent associés à une hypovolémie ou une hypervolémie, tels que l’hypotension, l’hypertension, les maux de tête et les nausées peuvent généralement être évités par une surveillance stricte de l’équilibre électrolytique du patient et par le contrôle du débit sanguin et du taux d’ultrafiltration.

Recommandations et précautions
Se reporter aux procédures spécifiques pour d’autres recommandations et précautions.

Emboîte gazeuse
Éviter la présence d’air dans le circuit extracorporel pendant le traitement. Si de l’air s’introduit dans le système, le traitement doit être interrompu et le sang ne doit pas être restitué au patient.

Réactions d’hypersensibilité
Il est recommandé d’interrompre le traitement si le patient présente des signes ou des symptômes de réactions d’hypersensibilité. Il est impératif de ne pas restituer au patient le sang contenu dans le circuit extracorporel au moment où la réaction a eu lieu.

Dialyseurs à haute perméabilité
Les dialyseurs EXELTRA ne doivent être utilisés qu’avec des générateurs de dialyse équipés d’un multiréacteur d’ultrafiltration ou d’un système précis de contrôle de l’équilibre de liquides.

L’utilisation du dialyseur EXELTRA dans des conditions cliniques de pression transmembranaire élevée peut entraîner un taux d’ultrafiltration net pouvant largement dépasser les besoins d’ultrafiltration de certains patients. Dans ces conditions, il est recommandé de ne pas restituer au patient une solution de réaction stérile est obligatoire.

Dialysat
L’utilisation d’un contrôle de conductivité en ligne est recommandée. Afin d’éviter une hémolyse, la température du dialysat ne doit jamais dépasser les 42 °C.

Procédure
1. S’assurez d’une asepsie rigoureuse.
2. Tous les raccordements doivent être soigneusement contrôlés avant et pendant le traitement.
3. Les pièges à bulles d’entrée (artérielle) et de sortie (veineuse) doivent toujours être ouverts. De l’air pouvant s’introduire à l’intérieur du circuit extracorporel en amont de la pompe à sang, l’utilisation d’un déteinteur de bulles d’air sur la ligne veineuse est recommandée.
4. Afin de préserver l’intégrité des membranes, ne pas dépasser une pression transmembranaire de 500 mmHg (66 kPa).
5. Il est recommandé de peser le patient avant et après le traitement afin de vérifier l’importance de l’ultrafiltration.
6. Différents produits de dialyse distribués par d’autres firmes peuvent être utilisés avec le matériel ou les produits de Baxter Healthcare Corporation. Comme Baxter n’est pas responsable des variations, des tolérances, de la résistance mécanique ou des modifications pouvant survenir à ces produits, Baxter ne peut garantir le bon fonctionnement des produits de dialyse des autres firmes lorsqu’ils sont connectés aux produits Baxter.
7. Si le patient est sous traitement médicamenteux, vérifier régulièrement les niveaux sanguins pour assurer le maintien de niveaux thérapeutiques appropriés.

Procédure de mise en route
Consultez la section Recommandations et précautions pour des instructions supplémentaires.

Ne pas utiliser si les protecteurs de stérilité des connecteurs sanguins ne sont pas à leur place.

Ne pas utiliser si l’emballage a été ouvert auparavant ou endommagé.

Montage initial
Connecter la ligne d’entrée (artérielle), la ligne de sortie (veineuse), les lignes de contrôle, la ligne d’administration de soluté et la ligne d’héparine (le cas échéant) au générateur de dialyse et au dialyseur.

Test à la pression du dialyseur
Bien que l’intégrité mécanique de ce dialyseur ait été testée, il peut toujours se produire en cours de traitement une rupture ou une fuite entraînant une perte de sang. C’est pourquoi il est recommandé de faire préalablement à l’utilisation un essai à la pression et d’exercer ensuite un contrôle permanent à l’aide d’un détecteur de fuite de sang placé sur la ligne du dialyseur. Une inspection visuelle du système est également recommandée.

1. Le test à la pression doit être exécuté avant le raccord du compartiment sang et dialysat du dialyseur.
2. Clamer la ligne de sortie (veineuse) en aval du piège à bulles, ainsi que toutes les autres tubulures nécessaires à la mise en place d’un système clos sur la ligne veineuse.
3. Avant d’activer la pompe à sang, s’assurer qu’il existe un office ouvert par lequel de l’air peut être aspiré dans la ligne d’entrée (artérielle) au travers d’un filtre bactérien tel qu’un isolateur de pression stérile. Actionner la pompe et augmenter lentement la pression dans le circuit extracorporel jusqu’à 300 mmHg (39,9 kPa) comme mesuré par le manomètre de pression veineuse.
4. Arrêter la pompe et clamer la ligne artérielle entre le dialyseur et la pompe.
5. Si la chute de pression est supérieure à 10 mmHg dans un délai de 30 secondes, vérifier qu’il n’y a pas d’erreur de clampage ou de raccordement avant de conclure à une fuite dans le dialyseur. Une chute de pression supérieure à 10 mmHg dans un délai de 30 secondes n’est pas acceptable et le dialyseur doit être remplacé.
Amorçage

* est indispensable de bien suivre les instructions de rinçage pour éliminer l'air et les sedus de l'intérieur du dispositif.

1. Placer le dialyseur dans son support, l'embout veineux du sang dirigé vers le haut. Remarque : il est important de maintenir le dialyseur dans cette position pendant l'amorçage du compartiment sang. Fermer les sorties du dialyseur à l'aide des protecteurs de stérilité des connecteurs sanguins (se référer à la figure 1).

2. Raccorder un nécessaire pour perfusion i.v. à une poche d'un litre de solution saline isotone stérile à 0,9 % comme suit :
   a. Dans le cas d'une ligne comportant un site d'injection de solution saline isotone, la solution peut être administrée par gravité au niveau de ce site. Lorsque la section entre le site et le connecteur de canule est purge d'air, clampé à proximité de ce connecteur.
   b. Si la ligne comporte un site d'amorçage avec capuchon sur la connexion patient, raccorder le nécessaire pour perfusion directement sur le site.

3. Faire circuler la solution saline isotone à travers le circuit extracorporel à un débit d'environ 200 ml/min.

4. Après avoir fait circuler environ 500 ml de solution saline isotone à 0,9 % dans le dialyseur et éliminé l'air, arrêter la pompe à sang et tourner le dialyseur de 180 ° pour que la sortie artérielle (rouge) se trouve vers le haut.

5. Retirer les protecteurs de stérilité des sorties dialyse. Fixer les connecteurs dialyse pour que la ligne d'entrée du dialyseur se trouve près de l'embout du sang veineux. Le sang et le dialyse doivent circuler en sens inverse. Mettre la pompe à sang en marche et faire couler le débit à un débit d'environ 500 ml/min. Réglage du taux d'ultrafiltration au minimum. Ne pas laisser la pression dans le compartiment dialyseur dépasser celle du compartiment sang. Il ne faut pas fonctionner le sac de solution saline à vide pour éviter l'entrée d'air dans le système.

6. Arrêter la pompe à sang après avoir rincé le circuit extracorporel avec 1000 ml de solution saline isotone stérile à 0,9 %. S'assurer que le compartiment canule est rempli de solution saline isotone.

7. Continuer à faire circuler le dialyseur pendant 5 minutes puis clamer les lignes artérielle et veineuse près du connecteur de la canule. Jeter le liquide d'amorçage utilisé. Le piège à bulles de la ligne veineuse devrait être aux 3/4 plein.

**Attention** : une fois le dialyseur amorcé et le circuit extracorporel purgé, régler le taux d'ultrafiltration au minimum. Ne pas laisser la pression du compartiment dialyseur dépasser celle du sang. Ceci permet de minimiser l'ultrafiltration du liquide d'amorçage du dialyseur entre le moment où le circuit est amorcé et le début du traitement. Si pour une raison quelconque la procédure ne commence pas immédiatement après l'amorçage, la solution saline isotone du circuit doit être immédiatement remplacée avec une nouvelle solution avant le début du traitement.

**Procédure**

Se référer à la section **Recommandations et précautions** pour des instructions supplémentaires.

Des instructions spécifiques seront données par le médecin traitant.

**Précautions** : l'utilisation du dialyseur avec les taux d'UF (ultrafiltration) net null ou à des taux d'UF nuls extrêmement bas peut entraîner une pression dans le compartiment dialyse supérieur à la pression du compartiment sang dans une partie du dialyseur. Comme la probabilité d'ultrafiltration inverse de dialyse non stérile dans le sang augmenté dans ces conditions, le taux d'ultrafiltration doit être soigneusement réglé selon les indications d'un médecin.

**Injection d'héparine**

Une héparinisation systématique ou locale peut être réalisée selon les instructions du médecin traitant.

**Démarrage du traitement**

Pour la configuration du circuit extracorporel, se référer à la figure 2.

**Attention** : observer attentivement le piège à bulles de sortie (veineuse) au moment où pénétrera le sang. Si ce dernier semble hémorragique, clamer la ligne de sortie (veineuse) et arrêter simultanément la pompe à sang. Clamer la ligne d'entrée (artérielle). Vérifier la formulation et les proportions du mélange puis chercher les autres causes possibles (surchauffe du dialyse, utilisation d'un liquide d'amorçage inadapté). Purger tout liquide incompatible du circuit de dialyse. Le sang ne doit pas être **injecté au patient**. Une fois la ligne qui l'entoure et corrigée, mettre le dialyseur et les eau au rebut. Installer un nouveau dialyseur et les lignes de dialyse et préparer le circuit selon les recommandations et précautions.
Sortie de la solution d'amorçage

Tête de sortie veineuse bleue

Entrée de la solution d'amorçage

Figure 1 - Orientation du dialyseur pendant l'amorçage du compartiment sanguin.

Figure 2 - Circuit extracorporel pour l'hémodialyse.

Trajet extracorporel stérile et apyrrogène.
Stérilisé par rayonnement gamma.

500 mmHg
66 kPa

Afin de préserver l'intégrité des fibres, ne pas laisser la pression transmembranaire excéder 66 kPa (500 mmHg) durant la dialyse.

À usage unique seulement.
EXELTRA 150 Data Sheet

Approximate Performance Characteristics

Note: Operation of the dialyzer under clinical conditions may produce values different from those illustrated because of the variables involved in the clinical dialysis procedure, in the cellulose triacetate membrane, and in the manufacture of the device. Therefore, the values given are for approximation only. See in-vitro test conditions for explanatory materials relating to the test conditions from which the data were derived.

Warning: These devices must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

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<td>EXELTRA 150</td>
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| Code Number       | SM2119               |
| Effective Surface Area (m²) | 1.5                  |
| Effective Length (mm)   | 230                 |
| Priming Volume (ml)    | 95                  |

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- Urea 100 193 262 305 332
- Creatinine 100 186 242 274 297
- Phosphate 99 179 227 255 274
- Vitamin B₁₂ 90 132 152 163 179
- Myoglobin 30 33 33 34 34

Ultrafiltration Rate (ml/hr/100mmHg) 3150

Hollow Fiber:
- Materials: Cellulose Triacetate
- Inner Diameter: 200 microns
- Membrane Thickness: 15 microns
- Sterilization: Gamma Irradiation

IN-VITRO TEST CONDITIONS

1. Clearance in compliance with the evaluation standards for dialyzer performances called for by the Japan Society of Artificial Organs.
   - Solute Concentration:
     - Urea 100 mg/dL
     - Creatinine 10 mg/dL
     - Phosphate 5 mEq/L
     - Vitamin B₁₂ 2 mg/dL
     - Myoglobin 10 mg/dL
     - Temperature: 37°C
     - Dialysate Flow: 500 mL/min
     - UFR: 0 mL/hr

2. Ultrafiltration rates were determined using bovine blood.
   - HCT: 25%
   - Blood Flow: 200 mL/min

3. Priming Volumes were determined using an aqueous solution.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
**EXELTRA 170 Data Sheet**

**Approximate Performance Characteristics**

Note: Operation of the dialyzer under clinical conditions may produce values different from those illustrated because of the variables involved in the clinical dialysis procedure, in the cellulose triacetate membrane, and in the manufacture of the device. Therefore, the values given are for approximation only. See in-vitro test conditions for explanatory materials relating to the test conditions from which the data were derived.

**Warning:** These devices must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

### Specifications of Performance

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<td>Membrane Thickness</td>
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<td>Sterilization</td>
<td>Gamma Irradiation</td>
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### In-vitro Test Conditions

1. Clearance in compliance with the evaluation standards for dialyzer performances called for by the Japan Society of Artificial Organs.
   - Solute Concentration: Urea 100 mg/dL, Creatinine 10 mg/dL, Phosphate 5 mEq/L, Vitamin B₁₂ 2 mg/dL, Myoglobin 10 mg/dL.
   - Test Solution: Dialysate
   - Temperature: 37°C
   - UFR: 0 mL/hr
   - Dialysate Flow: 500 mL/min

2. Ultrafiltration rates were determined using bovine blood:
   - HCT: 25%
   - Blood Flow: 200 mL/min

3. Priming Volumes were determined using an aqueous solution.

---

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Distributed by Distribu by

**Baxter Healthcare Corporation**

Deerfield, IL 60015 USA

Made in Japan/Fabriqué au Japon

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-1-36-770

2003/03

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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
Cellulose Triacetate Hollow Fiber Dialyzer

Introduction
This device is designed to conform to the U.S. Cellulose Triacetate Hollow Fiber Dialyzer. See data sheet for performance characteristics of accompanying oxygenator model. Deviation from described methods should be undertaken only under the supervision of or with the approval of a physician.

Note: This dialyzer is recommended for one use only.

Much of the original medical literature regarding dialyzer reuse describes risks and hazards associated with the practice. There is no evidence that reuse is intrinsically dangerous. There are some studies that report replication in a small number of patients treated in dialysis units that were long-term users (Beld et al. 1987). New concerns, however, have been raised regarding the risk of carboxybin as related to long-term exposure, fertilization, and arrest to formaldehyde (U.S. Bureau of the Census 1983). It is also recommended that dialysis machines and equipment be sterilized after use for each patient, and that dialysis solutions be sterilized by steam or radiation (Kaplan et al. 1983). In addition, the nephelometric method of demonstrating an acceptable residual level of formaldehyde has been reported to be a more reliable, more sensitive test for reutilization than the test used in this study (Lindberg et al. 1987). It has been suggested that standard procedures for rinsing, cleaning, and sterilization be developed and evaluated in prospective, randomized trials. The AAMI has developed guidelines (Recommended Practice for Reverse Osmosis Machines 1982) which could be used to develop procedures for the routine care of dialysis units, blood products, and the dialysis staff. Baxter Laboratories Corporation recommends that this dialyzer be discarded after a single use.

Since conditions of cleaning and sterilization after the first use are the responsibility of the attending physician or institution, dialysis units must be operated in a sterile, non-reusable, and capacious environment. This environment is appropriate to the needs of the patient.

Description
See data sheet for data concerning the specifications of the accompanying oxygenator model. The following guidelines are based on the typical use of the dialyzer. Other uses may be achieved by modification of the system. The fiber diameter may be increased or decreased by the manufacturer of the device.

High Permeability Dialyzers
High permeability dialyzers must be used only in conjunction with oxygenator machines equipped with an ultrasonic detector. An ultrasonic detector is necessary to prevent any dialyzing fluid from entering the patient or the dialyzer during malfunction or pilot pump running.

Actions
Some performance characteristics of the dialyzer are described in the accompanying data sheet. Performance data has been developed under indicated specific test conditions in vitro, in accordance with the Evaluation Standards for dialyzer performances established by the Japan Society for Artificial Organs. (Stratification characteristics have been measured using a test kit in vivo blood containing systems. Operations of the dialyzer under clinical conditions may produce different performance characteristics from those illustrated because of the variables involved in the clinical dialysis procedure, the cellulose triacetate membrane fibers, and the manufacturer of the device.

Indications
Intravenous dialysis with dialysis fluid is designed for patients with acute or chronic renal failure whose dialysis therapy is judged to be durable. It may also be used to indicate the treatment of patients requiring dialysis with protein or drugs (Plum and Plum 1974).

Selection of patients for the device should be undertaken only under the supervision of or with the approval of a physician who has evaluated all of the pertinent features of the patient's illness.

Adverse Reactions
Some patients have experienced apparent hyperosmolality reactions (septicaemia) associated with dialysis. Symptoms and signs have included intestinal disturbance, diarrhea, dysuria, or colic, peritonitis, and hypotension and facial edema. Uremia and edema may be associated with uremia, hyperosmolar urine, and edema may be associated with hyperosmolarity. Hyperglycemia, hypotension, and hypercalcaemia have been associated with equipment malfunction, dialysate and dialysate fluid removal from the patient during dialysis according to a preset fluid removal goal.

Warnings and Precautions
A. Hyperosmolality Reactions
It is recommended that dialysis be discontinued in any patient exhibiting signs or symptoms of a hyperosmolality reaction (see section on adverse reactions) and the appropriate treatment be undertaken (Kelly and Patterson 1974). It is also recommended that blood be contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient. Further it is recommended that the CTA Cellulose Triacetate Hollow Fiber Dialyzer be used only for such patients unless a particular medical indication exists and that the dialyzer should be used only in the presence of a physician. A physician is responsible for the timely service or maintenance for successful monitoring for such signs or symptoms during dialysis.

B. High Permeability Dialyzer
High permeability devices are defined as those devices with in vivo ultrasonication rates greater than 8 LS/in. Such devices must be used only in conjunction with dialysis machines equipped with an ultrasonication controller.

C. Dialysate Fluid
1. A dialysate fluid of the appropriate composition should be selected by a physician to suit the patient's needs.

2. Line or a conductivity meter to estimate proper mixing is recommended.

3. To avoid hyperosmotic dialysate fluid temperatures should never exceed 42°C (107.6°F).

D. Dialysis Procedures
1. Accurate technique must be employed to avoid contamination at the blood path when connecting the patient to the inlet (arterial) and outlet (venous) ports. After the dialysis fluid has been introduced into the dialysis machine and before the patient is connected, the hemodialyzer and the dialysis fluid should be sterilized.

2. All connections should be checked carefully before and during the first minutes of operation. At several times during dialysis, there should be visual inspections of the connections to detect leaks and avoid blood loss.

3. The outlet (venous) bubble trap must be full at all times to optimize bubble trapping capability.

4. See instructions accompanying the set. Since the possibility exists that air may be drawn into the extracorporeal circuit on the negative pressure side of the pump, the use of an air-free detector device on the venous line is recommended.

5. To avoid unnecessary blood trauma, the blood pump must be adjusted for proper aspiration of the pump segment tubing. Refer to instructions accompanying the dialysis pump and dialyzer testing set for proper procedures.

6. Use heavy duty tubing clamps or hemostats placed at right angles when clamping tubing. The use of heavy duty clamps minimizes fluid leakage.

7. Although this dialyzer has been tested for mechanical integrity, a rupturing or leak leading to blood loss can occur during dialysis. Therefore, both arterial and venous (See Pressure Testing Section) and constant monitoring by means of a hemophagocytic blood leak detector in the dialysate fluid line of the dialysis machine and visual inspection of the system are recommended.

8. If blood appears in the dialysis fluid, indicating a break, an attempt may be made (at the discretion of the attending physician) to return blood lines to the extracorporeal system to the patient (see Terminating Dialysis Section). If the decision is made not to return the blood to the patient, immediately clamp the arterial (inlet) and venous (outlet) connections and fill the blood pump and fluid delivery system. Sequentially clamp off the patient's cannula and disconnect from the inlet (arterial) and outlet (venous) sets. Close the patient's cannula and remove clamps to maintain blood flow. For patients with malfunction, patency of the fistula by flushing approximately 1 ml of heparinized priming fluid into each set. Remove the dialyzer and inlet sets from the machine and discard.

9. Carefully observe below knee chamber as blood filters. If blood appears hemorrhagic, clamp off the outlet (venous) set and simultaneously shut off the blood pump. Clamp off the inlet (arterial) set. Sequentially clamp the dialysate fluid sets and disconnect from the inlet (arterial) and outlet (venous) sets. Verify that the dialysate fluid mixture is correct or that the dialysis machine is providing proper perfusion, then test again (e.g., dialysate fluid temperature, proper priming fluids). Purge all incompatible fluid from the dialysate fluid path. The blood must not be returned to the patient. When clamps have been determined and corrected, discard the dialyzer and sets. Set up a new dialyzer and inlet sets and restart the circuit in the normal way for starting dialysis.

10. To preserve blood integrity, do not exceed 500 mmHg transmural bypass pressure.

11. Monitoring of the post-pump inlet (arterial) and outlet (venous) blood pressures should be done through dialyzer. This will detect certain problems indicated by high vein pressure and allow calculation of ITBP which is useful in the production of ultrasonic. A constant rise in inlet (arterial) pressure may indicate an obstruction in the dialyzer or lines leading to the patient. The increasing pressure may exceed the recommended ITBP of 500 mmHg. To monitor the inlet pressure, an inlet (arterial) set with a post-pump monitoring chamber may be used. See directions accompanying the set.

12. To preserve blood integrity, do not exceed 500 mmHg transmural bypass pressure.

13. In order to achieve extremely low ultraltration rates, the dialyzer pressure in a portion of the dialyzer may exceed the blood pressure. Under these circumstances, nonsterile dialyzer could potentially be introduced into the blood. Therefore, the ultraltration rate must be carefully adjusted as directed by a physician.

14. Due to the resulting increased residual blood volume, and the increased chance of air embolism in the patient, air mixing is not indicated.

15. Many dialysis products available from other manufacturers are used with equipment or disposables from Baxter Healthcare Corporation. Baxter has no control over variability, tolerances, mechanical strength or changes in these products which may be made from time to time. Therefore, Baxter cannot ensure that the dialysis products of other manufacturers, when connected with its products, will function in a satisfactory manner.

16. Refer to manufacturer's directions accompanying drugs and products to obtain full information for use in this procedure.
Preparing the Dialyzer

A. Pressure Testing

1. Place the dialyzer in the dialyzer holder.

2. Install pump segment of the inlet (arterial) set in the blood pump and adjust for proper connections. Use appropriate instructions accompanying sets.

3. Suspect the outlet (venous) set with the bubble trap in the venous position.

4. Acceptably remove the protectors from the inlet (arterial) set and dialyzer inlet port and connect.

5. Prime the dialyzer (outlet set) with the correct fluid.

6. Connect the monitoring line on the outlet (venous) set to the venous pressure monitor.

7. Clamp the outlet (venous) set below the bubble trap and any other tubes necessary to create a closed system on the venous side.

8. The dialysis pump and stop watch are set at 30 min as measured in the extracorporeal circuit to 300 mmHg as measured on the venous pressure monitor.

9. Turn off the blood pump and clamp off the inlet (arterial) set between the pump and the dialyzer.

10. Observe the drop in pressure in the blood compartment; any drop in pressure greater than 10 mmHg within 30 s is unacceptable and the dialyzer should be replaced. If a pressure drop greater than 10 mmHg occurs, check for a faulty clamp or connection before performing a dialyzer leak test.


B. Initial Set-Up

1. Fill the dialysis tubing with saline on the arterial and venous side.

2. Connect the correct monitoring line, saline administration line, and heparin line where applicable.

C. Priming the Dialyzer (Figure 3)

1. Place the dialyzer in the holder with the venous port directed upwards.

2. Close or plug the dialysate ports by clamping and connecting the dialysate lines to the dialyzer (the dialysate inlet line should be connected to the same end as the venous outlet).

3. Check to make sure the arterial and venous lines are connected securely to the dialyzer. Attach an IV Administration Set to a one liter container of heparinized saline and connect it to the saline administration port on the arterial side of the dialyzer. An additional liter of saline solution should be available for infusion during dialysis and for rinsing the extracorporeal circuit when terminating dialysis. Rinse the heparinized saline solution through the extracorporeal circuit at a flow rate of approximately 500 ml/min.

4. After approximately 500 ml of heparinized saline has been run through the dialyzer, unclamp the dialysate lines to the dialyzer and run dialysate at a flow rate of approximately 500 ml/min through a pressure of approximately 0 mmHg.

5. Turn the blood pump off after the extracorporeal circuit has been rinsed with 1000 ml of heparinized saline solution. Continue to run dialysate for another 5 min, then proceed to clamp the blood lines shown in Figure 5. Discuss the spent priming fluid. The venous bubble trap should be 3/4 full.

Caution: When the priming procedure has been completed, and the extracorporeal circuit is free of air, set the dialysate outlet (negative) pressure to approximately zero (0 mmHg). This will minimize the ultradilution of priming solution from the dialyzer between the flows when the circuit is primed and dialysis is to commence. Some ultradilution of the priming solution will occur (additional heparin saline may need to be added to the circuit to prevent all of the priming solution from being ultradiluted). If for any reason the dialysate process is not started immediately following the completion of the priming solution in the circuit should be dispensed with fresh solution immediately prior to the initiation of dialysis.

Administration of Heparin

Although heparin administration procedures vary, and are adjusted to the requirements of the individual patient by the attending physician, a proper heparinization schedule must be initiated before and maintained throughout dialysis to prevent clotting and subsequent blood path obstruction. The following are examples of heparinization schedules for hemodialysis (Gluck and Stern 1979).

1. Priming fluid should contain the following amounts of heparin:
   b. Noncrystalline heparinizing fluid (0.5% Sodium Chloride injection) (1000 ml solution) should contain 2000 USP Units of Heparin per 1000 ml solution.
   c. Add 50 USP Units of Heparin per 100 ml of dialysate.

2. A V.A. catheter set: catheters should be primed with a solution containing at least 100 USP Units of Heparin per 100 ml of solution.

3. Continuous Heparinization

Continuous heparinization is similar to intermittent heparinization except that following administration of the bolus dose, a heparinized pump is used to deliver heparin at a constant rate at the rate necessary to maintain the desired clotting time. Clotting time should be determined approximately at hourly intervals. A heparin pump delivery between 1000 - 3000 USP Units of Heparin per hour usually is sufficient.

A. Blood pressure is maintained at 140/90 mmHg or lower will be necessary to the infusion of solution. Follow equipment manufacturer's operating directions carefully.

B. Intravenous Heparinization

Patient should be heparinized systemically at least 1 hr, but not more than 2 hr, before hemodialysis (unless contraindicated by factors requiring regional heparinization). The bolus dose is usually 2000 to 4000 USP Units of heparin intravenously for the average adult. The loading dose should be adjusted to the patient's weight in order to establish a clotting time equivalent to a Low-White with a time of 25 to 30 min (obtained by either the Low-White or a phenolic blood test). The desired clotting time is usually between 100 and 150 min. If the time is not prolonged, the heparinized fluid should be administered at a rate of 2000 USP Units of Heparin per hour. If the time is 300 min, the heparin administration should be continued at a rate of 4000 USP Units of Heparin per hour.

C. Regional Heparinization

Regional heparinization would be better to diagnose bleeding. Regional heparinization, heparin to administration, heparin to alteration, heparin to procedure, heparin to monitor, and heparin to pressure monitoring line. The clotting time of blood from the pressure should be normal.


Figure 1 - Location of Blood Inlet and Outlet Ports, Dialyzing Fluid Inlet and Dialyzing Fluid Outlet Ports

Venous Pressure Monitor

Figure 2 - Air Testing of Dialyzer

NOT FOR PRODUCTION USE


Figure 3 - Dialyzer in Holder for Priming

Note: It is extremely important to keep the dialyzer in this position during priming of blood compartment until all air is removed.

Figure 4 - Extracorporeal Circuit for First Step in Priming Procedure

Figure 5 - Extracorporeal Circuit for Second Step in Priming Procedure
Sterile, nonpyrogenic blood path. Sterilized by gamma irradiation. Do not use if tip protectors are not in place. Blood and dialyzing fluid should flow countercurrently. See accompanying directions. This dialyzer is recommended for one time use only. Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.

Warning: This device must be used on dialysis machines with an ultrafiltration controller.

Pantone 287 Blue
Baxter

CTM

Cellulose Trisacetate
Hollow Fiber Dialyzer

Model CT-190G

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

Distributed by Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in Japan

Sterile, nonpyrogenic blood path. Sterilized by gamma irradiation. Do not use if any protections are not in place.
Blood and dialyzing fluid should flow countercurrently. See accompanying directions.

This dialyzer is recommended for one use only. Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.

Warning: This device must be used on dialysis machines with an ultrafiltration controller.

7-26-1-290
9371

Pantone 287 Blue
CT™ Cellulose Triacetate High Efficiency Hollow Fiber Dialyzer
Model CT•110G

Sterile, nonpyrogenic blood path
Sterilized by gamma irradiation.
Do not use if tip protectors are not in place.
Blood and dialyzing fluid should flow countercurrently.
Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.
See accompanying directions.

Distributed by
Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in Japan
7-7-1-894 83/3

This dialyzer is recommended for one time use only.
Caution: Federal (USA) law restricts this device to sale by or on order of a physician.
Warning: This device must be used on dialysis machines equipped with an ultrafiltration controller.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
CT™ Cellulose Triacetate High Efficiency Hollow Fiber Dialyzer
Model CT•190G

Sterile, nonpyrogenic blood path
Sterilized by gamma irradiation.
Do not use if tip protectors are not in place.
Blood and dialyzing fluid should flow countercurrently.
Do not store above 40°C (104°F). Avoid excessive changes in relative humidity.
See accompanying directions.

Distributed by
Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in Japan
7-7-1-806 8343

This dialyzer is recommended for one time use only.
Caution: Federal (USA) law restricts this device to sale by or on order of a physician.
Warning: This device must be used on dialysis machines equipped with an ultrafiltration controller.
CT™ Cellulose Triacetate Hollow Fiber Dialyzers
See accompanying directions for CT™ Cellulose Triacetate Dialyzers.
**SPECIFICATIONS/PERFORMANCE**

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<td>76 mL</td>
<td>95 mL</td>
<td>115 mL</td>
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- **Clearances (mL/min)**
  - Urea: 189, 192, 193, 197
  - Creatinine: 158, 177, 186, 189
  - Phosphatase: 150, 171, 179, 186
  - Uric Acid: 154, 173, 172, 143
  - Myoglobin: 22, 26, 32, 38

- **Ultrafiltration Rate (mL/100mmHg)**
  - 2130

**IN-VITRO TEST CONDITIONS**

1. Clearance in compliance with the evaluation standards for dialysis performances called for by the Japan Society of Artificial Organs.
2. UFR: Bovine Blood

**SOLUTE CONCENTRATION (mg/dL)**

- Urea: 100
- Creatinine: 10
- Phosphatase: 5
- Uric Acid: 10
- Myoglobin: 10

**TEST SOLUTION**

- Temperature: 37°C
- TMP: 0 mmHg
- Blood Flow: 200 mL/min
- Dialysate Flow: 500 mL/min

**CT™ DIALYZER ULTRAFILTRATION DATA**

Approximate Performance Characteristics

Note: Operation of the dialyzer under clinical conditions may produce values different from those illustrated because of the variables involved in the clinical dialysis procedure, in the cellulose triacetate membrane, and in the manufacture of the device. Therefore, the values given above are for approximation only. See further explanatory material in the text relating to the test conditions from which the data were derived.

**Warning:** High permeability dialyzers are defined as those devices with in vivo ultrafiltration rates greater than 8.0 mL/hr/mmHg. These devices must be used on dialysis machines equipped with an ultrafiltration controller.

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Made in Japan


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Iss. June 1994

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7-7-21/94

[Handwritten notes]
### EXELTRA™ HIGH FLUX DIALYZERS

#### MATERIAL LIST

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
# EXELTRA™ HIGH FLUX DIALYZERS

## PHYSICAL CHARACTERISTICS

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![Diagram](image)

1. CASE (HOUSING)
2. HEADER
3. O-RING
4. HEADER CAP (TIP PROTECTOR)
5. POTTING COMPOUND
6. HOLLOW FIBER

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

CHEMICAL STRUCTURE

The membrane used in the Baxter EXELTRA™ dialyzers is manufactured using the same cellulose triacetate material as the previously cleared CT™ dialyzer membrane. This cellulose triacetate material is produced using an acetylation process which substitutes about 90% of the hydroxyl groups (-OH) in cellulose with acetyl groups (CH₃CO-). The resulting material (polymer) is then extruded into hollow fibers by the Toyobo Co., Ltd. The Nipro Corporation has calculated the pore size to be 70Å radius for the EXELTRA™ membrane.
EXELTRA 150 and EXELTRA 170, Single Use Dialyzers

Declaration of Conformity with Design Controls

Verification Activities
To the best of my knowledge, the verification and validation activities, as required by the risk analysis, for the above referenced Medical Devices were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Thomas Hiller
Director, Quality Assurance
Baxter Healthcare Corporation

3/25/03

Manufacturing Facility
(b) (4) manufacturing facility in (b) (4) has been audited by Baxter Healthcare Corporation and is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Allen T. Range
Manager, Supplier Quality Assessment
Baxter Healthcare Corporation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
EXELTRA 150 and EXELTRA 170, Single Use Dialyzers

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, the verification and validation activities, as required by the risk analysis, for the above referenced Medical Devices were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Thomas Hiller
Director, Quality Assurance
Baxter Healthcare Corporation

Date

Manufacturing Facility

(b) (4) manufacturing facility in (b) (4) has been audited by Baxter Healthcare Corporation and is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Allen T. Range
Manager, Supplier Quality Assessment
Baxter Healthcare Corporation

Date
March 13, 2003
Memorandum

From: Reviewer(s) - Name(s)  Gema González

Subject: 510(k) Number  K030974

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. Per 510K paradigm, Sponsor has reached SE determination for Special
☐ 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)

Animal Tissue Source ☐ 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

Predicate Product Code with class:

Class II, 78 KDI, 876.5860

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

Review:

(Branch Chief)

GRDB 4/25/03

(Date)

Final Review:

(Branch Chief)

David A. Segerson 4/25

(Date)

Revised: 8/17/99

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS

1. **New Device is Compared to Marketed Device**

2. **Descriptive Information about New or Marketed Device Requested as Needed**

3. **Does New Device Have Same Indication Statement?**
   - NO

4. **Do the Differences Alter the Intended Therapeutic/Diagnostic/etc. Effect (in deciding, may consider impact on Safety and Effectiveness)?**
   - YES => Not Substantially Equivalent Determination
   - NO

5. **New Device Has Same Intended Use and May be "Substantially Equivalent"**

6. **Does New Device Have Same Technological Characteristics, e.g. Design, Materials, etc.?**
   - NO

7. **Could the New Characteristics Affect Safety or Effectiveness?**
   - YES
   - NO

8. **Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?**
   - YES
   - NO

9. **Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?**
   - NO

10. **Are Performance Data Available to Assess Equivalence?**
    - YES
    - NO

11. **Performance Data Required**
    - Performance Data Demonstrate Equivalence?
      - YES
      - NO
      - To A

12. **Performance Data Demonstrate Equivalence?**
    - YES
    - NO
    - "Substantially Equivalent" Determination

---

- **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.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
To: THE FILE  
RE: DOCUMENT NUMBER  K030974

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Reserved Class I device. The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

2. Submitter's statement that the INDICATION/INTENDED USE of the modified device as described in its labeling HAS NOT CHANGED along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.

3. A description of the device MODIFICATION(S), including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the FUNDAMENTAL SCIENTIFIC TECHNOLOGY of the modified device has not changed.

4. Comparison Information (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics. – Addition of 1.5 m² and 1.7 m² dialyzers to dialyzer family (changes in numbers of fibers and fiber lengths).

5. A Design Control Activities Summary which includes:
   a) 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
   b) 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
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) 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, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I acknowledge the sponsor's determination of substantial equivalent to the previously cleared (or their preamendment) device.
MEMORANDUM

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

DATE: April 24, 2003

FROM: Biomedical Engineer, GRDB/DRARD, HFZ-470

SUBJECT: K030974 – Baxter Healthcare Corporation
EXELTRA™ 150 and EXELTRA™ 170 Dialyzers, Single Use

Special 510(k)

TO: The Record

The proposed device is a single-use dialyzer, the EXELTRA™ Plus 210 dialyzer, which is a modification of the previously cleared CT110G and CT190G dialyzers (K890315, K926568, and K970663). The classification is Class II, 21 CFR §876.5860. The product code is 78KDI.

This document was submitted under the Special 510(k) program. Because it represents a slight change in the number of fibers, resulting in an increased surface area, it is my opinion that, through the use of appropriate design controls and design verification activities, a substantial equivalence determination may be reached by the sponsor. This submission, therefore, is eligible for review as a Special 510(k).

Intended Use:

The proposed devices are indicated for patients with acute and chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients with poisons or drug overdose.

Note: At the request of FDA, the sponsor has modified this statement to be consistent with that of the predicate device. As revised, the statement is adequate.

Device Description:

The sponsor has noted that the proposed EXELTRA™ 150 and 170 devices are cellulose triacetate hollow fiber dialyzers that will be labeled for single use. Their casing and header are fabricated of polycarbonate and they contain silicone O-rings, polyethylene header caps, and polyurethane potting compounds. In use, like other hollow fiber dialyzers, blood traverses through the hollow fibers while dialysate flows, typically in a counter-current fashion, in the dialysate compartment of the device, which encircles the hollow fiber bundle. With the flow of
blood and dialysate, diffusion occurs through the fiber membrane, thus enabling the clearance of solutes and toxins from the patient’s blood. The sponsor has explained that the proposed devices’ design, including the materials of construction, have not been altered from those of the predicate device. They both share the identical cellulose triacetate membrane. The differences introduced in the current submission consist of changes in the number of fibers used, resulting in increases in the proposed dialyzers’ surface areas, and the introduction of the EXELTRA™ name.

The sponsor has presented the following device specifications throughout the submission:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Proposed EXELTRA™ 150</th>
<th>Proposed EXELTRA™ 170</th>
<th>Predicate CT110G</th>
<th>Predicate CT190G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surface Area, m²</td>
<td>1.5</td>
<td>1.7</td>
<td>1.1</td>
<td>1.9</td>
</tr>
<tr>
<td>Effective Fiber Length, mm</td>
<td>230</td>
<td>239</td>
<td>206</td>
<td>248</td>
</tr>
<tr>
<td>Priming Volume, ml</td>
<td>95</td>
<td>105</td>
<td>70</td>
<td>115</td>
</tr>
<tr>
<td>Number of Fibers</td>
<td>10,300</td>
<td>11,300</td>
<td>8,400</td>
<td>12,100</td>
</tr>
<tr>
<td>Fiber Inner Diameter, µm</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
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<tr>
<td>Fiber Thickness, µm</td>
<td>15</td>
<td>15</td>
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</tr>
<tr>
<td>Fiber Material</td>
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<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Number of Fibers</td>
<td>10,300</td>
<td>11,300</td>
<td>8400</td>
<td>12,100</td>
</tr>
<tr>
<td>Ultrafiltration Rate, ml/hr/100 mm Hg *</td>
<td>3159</td>
<td>3380</td>
<td>2454</td>
<td>3642</td>
</tr>
<tr>
<td>Solute Clearances **</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urea</td>
<td>193</td>
<td>196</td>
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<td>Creatinine</td>
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<td>Phosphate</td>
<td>179</td>
<td>179</td>
<td>161</td>
<td>186</td>
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<tr>
<td>Vitamin B₁₂</td>
<td>132</td>
<td>138</td>
<td>113</td>
<td>143</td>
</tr>
<tr>
<td>Myoglobin</td>
<td>33</td>
<td>39</td>
<td>26</td>
<td>38</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Gamma Irradiation</td>
<td>Gamma</td>
<td>Gamma</td>
<td>Gamma</td>
</tr>
</tbody>
</table>

* For the ultrafiltration data, the blood flow rate was 200 ml/min.
** Solute clearance data obtained with a dialysate of the following concentrations: 100 mg/dL urea, 10 mg/dL creatinine, 5 mEq/L phosphate, 2 mg/dL Vitamin B₁₂, and 10 mg/dL myoglobin. The UFR was set at 0 ml/hr. The solute clearance data reported in the table above were obtained at a blood flow rate of 200 ml/min and dialysate flow rate of 500 ml/min. Data obtained at Qₘ of 100, 300, 400, and 500 ml/min were also reported.

It should be noted that the data described above were included in the proposed labeling. The data and information appear adequate.

As discussed above, no materials changes have been implemented. As a result, no biocompatibility issues remain at this time. However, in an effort to address the changes implemented, the sponsor performed a Clinical Hazard Analysis, Failure Modes and Effects
Analysis (FMEA). As a result of this analysis, the sponsor concluded that no additional verification and validation testing was required. When asked about this, the sponsor explained that no new types of tests were deemed necessary, however, functionality tests were performed, as they are for any Baxter dialyzer (i.e., ultrafiltration coefficients, solute clearances, priming volume, dimensional verifications, etc). Furthermore, the sponsor has indicated that all tests performed used the same acceptance criteria as those used for the predicate devices. Judging from the data provided in the proposed labeling, most of the required tests, as per FDA’s guidance document for hemodialyzers, have been performed, with the exception of pressure drop tests for the dialyzer’s blood and dialysate sides. This test is necessary, since the fibers’ lengths have changed, and the dimensions of the dialyzer casing have also been modified to accommodate the increased numbers of fibers. Changes in these parameters may affect the flow characteristics within the dialyzer. This was brought to the attention of the sponsor, who provided a justification for why these data were deemed unnecessary. According to the sponsor, the fiber lengths and numbers of fibers used for the proposed EXELTRA™ 150 and 170 dialyzers are the same as those used for the Baxter CA-HP-150 and CA-HP-170 dialyzers (K950454 and K950522). Also, these dialyzers share the same casing dimensions, fiber inside diameters and fiber thicknesses. As a result, the pressure drop data obtained for the CA-HP-150 and CA-HP-170 dialyzers should also be applicable to the proposed EXELTRA™ dialyzers. This is adequate.

The sponsor has noted that the proposed dialyzer will be sterilized with gamma irradiation, just as the predicate devices. The sterilization dose is based on ANSI/AAMI/ISO-11137 Method 2B. The sterility assurance level (SAL) will be $10^{-6}$. Regarding the packaging, the sponsor has also explained that it remains unchanged from that which was cleared for the predicate device under K970663. This information is adequate.

The sponsor has provided labeling for the proposed device in the form of package labels, carton labels, and package inserts. The package labels adequately identify the proposed device as a single-use dialyzer. They also have manufacturer information, maximum transmembrane pressure (TMP), the method of sterilization, lot number, surface area (through device’s name), and an expiration date. The package inserts include the dialyzer’s indications for use, a list of common adverse events, warnings and cautions, instructions for the priming of the dialyzers, as well as for running treatments, and diagrams of how the device is connected within the extracorporeal circuit. Among the warnings and cautions, the sponsor has noted that the proposed dialyzer should only be used with machines equipped with an ultrafiltration controller, and that sterile infusion fluid may be needed to replenish patients who become hypovolemic. The user is also warned against surpassing the maximum TMP, using aseptic techniques, waste disposal issues, and procedure problems which may lead to hemolysis. Finally, the package insert information contains a data sheet with a summary of the proposed dialyzer’s performance specifications. In summary, the provided labeling is adequate and consistent with that of the predicate devices. At the request of FDA, the proposed package insert has been modified to reflect the predicate device’s indications for use statement. This is adequate.
Regarding the proposed device’s expiration date, the sponsor has noted that a three year shelf life will be specified. This is consistent with the predicate device’s shelf life, therefore, no additional validation information is necessary at this time. However, it should be noted that accelerated and real time data have been provided for the EXELTRA™ Plus 210 Dialyzer, which is currently under review (K030975). In that submission, the dialyzer membrane’s manufacturing has been changed slightly, however, that device’s membrane chemical formulation is identical to that of the proposed dialyzers. In summary, the proposed three year shelf life is adequate.

**Recommend:** Submission be found substantially equivalent to the predicate devices and to devices under 876.5860, High permeability hemodialysis system.

Gema González 4/25/03

[Signature]

4/25/03
I am providing you with the information you requested via voice mail on April 24, 2003 and our phone conversation of April 25, 2003. Included in this FAX correspondence are revised Indications for Use sheets and revised draft package inserts incorporating the revised indications for use statement for both K030974 and K030975.

Regarding the pressure drop information, the subject Excltra and Excltra Plus dialyzers use the same case, the same case length, the same fiber count, the same fiber length, the same fiber internal diameter, the same effective length and the same priming volume as has been previously cleared for similar models (i.e., fiber surface area) of Baxter’s CAHP dialyzers under K950454 and K950522. We have attached the data sheets and pressure drop performance data for the CAHP dialyzers cleared under those 510(k) premarket notification applications. The specific fiber counts for the subject dialyzers are as follows: Excltra 150 - 10,300, Excltra 170 - 11,300, Excltra Plus 210 - 13,000. This information was provided in the original 510(k)s as page 41 in K030974 and page 42 in K030975. These are also the exact same fiber counts for the comparable CAHP dialyzer models.

All tests and acceptance criteria performed for the subject Excltra and Excltra Plus dialyzers submitted under K030974 and K030975 are the same as those tests and acceptance criteria for the predicate dialyzers.

If you have any questions, please contact me at 847-473-6079.

Sincerely,

David E. Curtin
K030974

Revised Indications for Use Sheet and Revised Draft Package Insert
Indications for Use Statement

510(k) Number (if known): ____________________

Device Name: EXELTRA™ Dialyzer

Indications For Use:

Hemodialysis with the EXELTRA™ Dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.
EXELTRA High Flux Dialyzers
Directions for Use

Baxter cannot warrant the sterility, nonpyrogenicity, mechanical integrity or performance of this dialyzer when reused. Deviation from described method should be undertaken only under the supervision or with the approval of a physician. See specific data sheet for performance characteristics.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

Caution for Storage
Store at 0°C to 40°C, avoiding direct exposure to sunlight and vibrations.

Avoid excessive changes in relative humidity. 

Indications
Hemodialysis with EXELTRA dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs. The device should be used only on the direction of a physician.

Contraindications
There are no special contraindications for use of this dialyzer for the hemodialysis procedure. Patients with a history of allergic reactions to Cellulose Trisatect should not be treated using this product.

Adverse Reactions
Patients may experience hypersensitivity (allergic) reactions during treatment.

Symptoms and signs have included asthma-like reactions, respiratory arrest, pruritus, urticaria, peripheral and facial edema, hypertension, hypotension, and cardiac arrhythmia. A history of allergic responses, including asthma, is an indication for careful monitoring for such signs or symptoms during treatment.

Side effects such as hypotension, hypertension, headache and nausea, which may be associated with hypovolemia or hypervolemia, can usually be avoided by careful management of the patient's fluid, electrolyte balance, blood flow rate and ultrafiltration rate.

Warnings and Precautions
Refer to specific procedures for additional warnings and precautions.

WARNING: The performance properties of reused EXELTRA dialyzers have not been established and procedures for disinfectant procedures have not been validated. Ineffective removal of residual disinfectant may lead to adverse patient reactions.

Air Embolism
Air in the extracorporeal circuit during treatment must be avoided. If air gets into the system, the treatment must be discontinued and the blood must not be returned to the patient.

Hypersensitivity Reactions
It is recommended that treatment be discontinued in any patient exhibiting signs or symptoms of a hypersensitivity reaction. The blood contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient.

High Permeability Dialyzers
EXELTRA dialyzers must be used only in conjunction with dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

Use of the EXELTRA dialyzer under clinical conditions of high transmembrane pressure may result in net ultrafiltration rates that greatly exceed the ultrafiltration requirements of some patients. Under these conditions, the use of sterile replacement fluid is mandatory.

Diayate Fluid
Use of an in-line conductivity monitor is recommended. To avoid hemolysis, dialysate temperature should never exceed 42°C (107.6°F).

Treatment Procedure
1. Aseptic technique must be employed.
2. All connections should be checked carefully before and during treatment.
3. The inlet (arterial) and outlet (venous) air bubble traps must be 3/4 full at all times. Since air may be drawn into the extracorporal circuit on the negative pressure side of the blood pump, the use of an air bubble detector on the venous line is recommended.
4. To preserve fiber integrity, do not exceed 500 mmHg (56 kPa) transmembrane pressure.
5. Weighing the patient before and after treatment is recommended to verify the extent of ultrafiltration.
6. Many dialysis products and other manufacturers are used with equipment or disposables from Baxter Healthcare Corporation. Baxter has no control over variability, tolerances, mechanical strength, or other characteristics.
7. If the patient is under drug therapy, blood levels must be monitored to ensure appropriate therapeutic levels are maintained.

Set Up Procedure
Refer to Warnings and Precautions section for additional statements.
Do not use blood port tip protectors when not in place.
Do not use if package has been previously opened or damaged.

Initial Assembly
Connect the inlet (arterial) set, outlet (venous) set, monitoring lines, saline administration line, and heparin line (where applicable) to the dialysis machine and dialyzer.

Air Testing
Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, air leak testing before use, constant monitoring by a blood leak detector on the dialysate fluid line, and visual inspection of the system is recommended.

1. Air testing should be completed prior to wetting either the blood or dialysate sides of the dialyzer.
2. Clamp the outlet (venous) set below the bubble trap and any other tubes necessary to create a closed system on the venous side.
3. Prior to turning on the blood pump, make sure there is an open port through which air can be drawn into the inlet (arterial) set through a bacterial barrier such as a sterile pressure transducer isolator. Turn on the blood pump and slowly increase the pressure in the extracorporeal circuit to 300 mmHg (38.5 kPa) as measured on the venous pressure monitor.
4. Turn off the blood pump and clamp off the inlet (arterial) set between the pump and the dialyzer.
5. If a pressure drop greater than 10 mmHg within 30 seconds occurs, check for a faulty clamp or connection before assuming a dialyzer leak exists. A confirmed drop in pressure greater than 10 mmHg within 30 seconds is not acceptable and the dialyzer should be replaced.
K030975

Revised Indications for Use Sheet and Revised Draft Package Insert
Indications for Use Statement

510(k) Number (if known): ______________________

Device Name: EXELTRA™ Plus Dialyzer

Indications For Use:

Hemodialysis with the EXELTRA™ Plus Dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

(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)
EXELTRA Plus High Flux Dialyzers
Directions for Use

Baxter cannot warrant the sterility, nonpyrogenicity, mechanical integrity or performance of this dialyzer when reused. Deviation from described method should be undertaken only under the supervision of a physician. See specific data sheet for performance characteristics.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

Caution for Storage
Store at 0°C to 40°C, avoiding direct exposure to sunlight and vibrations.
Avoid excessive changes in relative humidity.

Indications
Hemodialysis with EXELTRA Plus dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.
The device should be used only on the direction of a physician.

Contraindications
There are no special contraindications for use of this dialyzer for the hemodialysis procedure. Patients with a history of allergic reactions to Cellulose Triacetate should not be treated using this product.

Adverse Reactions
Patients may experience hypersensitivity (allergic) reactions during treatment.
Symptoms and signs may include asthmatic reactions, respiratory arrest, pruritus, urticaria, erythema, peripheral and facial edema, hypertension, hypotension, and cardiac arrhythmia.
A history of allergic responses, including asthma, is an indication for careful monitoring for such signs or symptoms during treatment.
Side effects such as hypotension, hypertension, headache and nausea, which may be associated with hypovolemia or hypervolemia, can usually be avoided by careful management of the patient's fluid, electrolyte balance, blood flow rate and ultrafiltration rate.

Warnings and Precautions
Refer to specific procedures for additional warnings and precautions.

WARNING: The performance properties of reused EXELTRA Plus dialyzers have not been established and procedures for disinfectant procedures have not been validated. Ineffective removal of residual disinfectant may lead to adverse patient reactions.

Air Embolism
Air in the extracorporeal circuit during treatment must be avoided. If air enters into the system, the treatment must be discontinued and the blood must not be returned to the patient.

Hypersensitivity Reactions
It is recommended that treatment be discontinued in any patient exhibiting signs or symptoms of a hypersensitivity reaction. The blood contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient.

High Permeability Dialyzers
EXELTRA Plus dialyzers must be used only in conjunction with dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

Use of the EXELTRA Plus dialyzer under clinical conditions of high transmembrane pressure may result in net ultrafiltration rates that greatly exceed the ultrafiltration requirements of some patients. Under these conditions, the use of sterile reinfusion fluid is mandatory.

Exeltra Fluid
Use of an in-line conductivity monitor is recommended. To avoid hemolysis, dialysate temperature should never exceed 42°C (107.6°F).

Treatment Procedure
1. Aseptic technique must be employed.
2. All connections should be checked carefully before and during treatment.
3. The inlet (arterial) and outlet (venous) air bubble traps must be 3/4 full at all times. Since air may be drawn into the extracorporeal circuit on the negative pressure side of the blood pump, the use of an air bubble detector on the venous line is recommended.
4. To preserve fibrin integrity, do not exceed 500 mmHg (66 kPa) transmembrane pressure.
5. Weighing the patient before and after treatment is recommended to verify the extent of ultrafiltration.
6. Many dialysis products available from other manufacturers are used with equipment or disposables from Baxter Healthcare Corporation. Baxter has no control over variability, tolerances, mechanical strength or changes in the products which may be made from time to time. Therefore, Baxter cannot ensure that the dialysis products of other manufacturers, when connected with its products, will function in a satisfactory manner.
7. If the patient is under drug therapy, blood levels must be monitored to assure appropriate therapeutic levels are maintained.

Set Up Procedure
Refer to Warnings and Precautions section for additional statements.
Do not use if blood port protectors are not in place.
Do not use if package has been previously opened or damaged.

Initial Assembly
Connect the inlet (arterial) set, outlet (venous) set, monitoring lines, saline administration line and heparin line (where applicable) to the dialysis machine and dialyzer.

Air Testing
Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, air leak testing before use, constant monitoring by a blood leak detector on the dialysate fluid line, and visual inspection of the system is recommended.

1. Air testing should be completed prior to wetting either the blood or dialysate sides of the dialyzer.
2. Clamp the outlet (venous) set below the bubble trap and any other tubes necessary to create a closed system on the venous side.
3. Prior to turning on the blood pump, make sure there is an open port through which air can be drained into the inlet (arterial) set through a bacterial barrier such as a sterile pressure transducer isolator. Turn on the blood pump and slowly increase the pressure in the extracorporeal circuit to 300 mmHg (39.9 kPa) as measured on the venous pressure monitor.
4. Turn off the blood pump and clamp off the inlet (arterial) set between the pump and the dialyzer.
5. If a pressure drop greater than 10 mmHg within 30 seconds occurs, check for a faulty clamp or connection before assuming a dialyzer leak exists. A confirmed drop in pressure greater than 10 mmHg within 30 seconds is not acceptable and the dialyzer should be replaced.
CAHP Dialyzer Data Sheets and Pressure Drop Information
### Specifications/Performance

<table>
<thead>
<tr>
<th>Model</th>
<th>CA-HP-80</th>
<th>CA-HP-110</th>
<th>CA-HP-150</th>
<th>CA-HP-170</th>
<th>CA-HP-210</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code Number</td>
<td>524721</td>
<td>524722</td>
<td>524723</td>
<td>524725</td>
<td>524726</td>
</tr>
<tr>
<td>Effective Surface Area (m²)</td>
<td>0.9 m², 1.1 m², 1.5 m², 1.7 m², 2.1 m²</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effective Length</td>
<td>194 mm, 204 mm, 230 mm, 238 mm, 247 mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Priming Volume</td>
<td>60 mL, 70 mL, 95 mL, 105 mL, 125 mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clearances (mL/min)</th>
<th>Urea</th>
<th>Creatinine</th>
<th>Phosphate</th>
<th>Vitamin B₁₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urea</td>
<td>172</td>
<td>177</td>
<td>187</td>
<td>182</td>
</tr>
<tr>
<td>Creatinine</td>
<td>148</td>
<td>156</td>
<td>174</td>
<td>181</td>
</tr>
<tr>
<td>Phosphate</td>
<td>115</td>
<td>128</td>
<td>147</td>
<td>156</td>
</tr>
<tr>
<td>Vitamin B₁₂</td>
<td>80</td>
<td>72</td>
<td>88</td>
<td>94</td>
</tr>
</tbody>
</table>

| Ultrafiltration Rate (mL/hr/mmHg) | 5.6 | 6.8 | 11.1 | 12.8 | 16.4 |

<table>
<thead>
<tr>
<th>Hollow Fiber</th>
<th>Material</th>
<th>Cellulose Diacetate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inner Diameter</td>
<td>200 microns</td>
<td></td>
</tr>
<tr>
<td>Membrane Thickness</td>
<td>15 microns</td>
<td></td>
</tr>
</tbody>
</table>

### In-Vitro Test Conditions

1. Clearance in compliance with the evaluation standards for dialyzer performances called for by the Japan Society of Artificial Organs. Solute Concentration: Test Solution: Dialysate: Urea: 100 mg/dL
   Creatinine: 10 mg/dL
   Phosphate: 5 mg/dL
   Vitamin B₁₂: 2 mg/dL
   Blood Flow: 200 mL/min

2. Ultrafiltration Rates were determined using Bovine Blood. HCT: 25% TMP: 150 mmHg

3. Priming Volumes were determined using an Aqueous Solution.

### Specifications of Module

- Housing: Polycarbonate
- Fitting Compound: Polyurethane
- Maximum Pressure: 500 mmHg

### CA-HP Dialyzer Ultrafiltration Data

![Graph showing ultrafiltration data]

Approximate Performance Characteristics

Note: Operation of the dialyzer under clinical conditions may produce different values from those illustrated because of the variables involved in the clinical dialysis procedure, in the cellulose diacetate membrane, and in the manufacture of the device. Therefore, the values given above are for approximation only. See further explanatory material in the IN-VITRO TEST CONDITIONS section as to the test conditions from which the data were derived.

Warning: High permeability dialyzers are defined as those devices with in-vivo ultrafiltration rates greater than 8.0 mL/hr/mmHg. These devices must be used on dialysis machines equipped with an ultrafiltration controller.

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7-19-2-363
Iss. March 1994
# PERFORMANCE COMPARISONS

CAHP High Performance Cellulose Diacetate Hollow Fiber Dialyzers

<table>
<thead>
<tr>
<th>Model Number</th>
<th>CAHP-110</th>
<th>CA-110</th>
<th>CAHP-130</th>
<th>CA-130</th>
<th>CAHP-150</th>
<th>CA-150</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code Number</td>
<td>5M2732</td>
<td>5M1732</td>
<td>5M2733</td>
<td>5M1733</td>
<td>5M2734</td>
<td>5M1734</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pressure Drop (mmHg)</th>
<th>CAHP-110</th>
<th>CA-110</th>
<th>CAHP-130</th>
<th>CA-130</th>
<th>CAHP-150</th>
<th>CA-150</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Side</td>
<td>41</td>
<td>41</td>
<td>37</td>
<td>37</td>
<td>36</td>
<td>36</td>
</tr>
<tr>
<td>Dialysate Side</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clearances (mL/min)</th>
<th>CAHP-110</th>
<th>CA-110</th>
<th>CAHP-130</th>
<th>CA-130</th>
<th>CAHP-150</th>
<th>CA-150</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urea (BUN)</td>
<td>177</td>
<td>172</td>
<td>186</td>
<td>179</td>
<td>187</td>
<td>183</td>
</tr>
<tr>
<td>Creatinine</td>
<td>156</td>
<td>145</td>
<td>165</td>
<td>153</td>
<td>174</td>
<td>162</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>70</td>
<td>50</td>
<td>79</td>
<td>57</td>
<td>88</td>
<td>63</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ultrafiltration Rate (mL/hr/mmHg)</th>
<th>CAHP-110</th>
<th>CA-110</th>
<th>CAHP-130</th>
<th>CA-130</th>
<th>CAHP-150</th>
<th>CA-150</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8.8</td>
<td>4.9</td>
<td>10.1</td>
<td>5.7</td>
<td>11.1</td>
<td>7.1</td>
</tr>
</tbody>
</table>

Note: Performance Data reported here are *In Vitro* results.

Clearance Data reported here were determined at Transmembrane Pressure = 0 mmHg, Blood Flow Rate = 200 mL/min, and Dialysate Flow Rate = 500 mL/min.

Ultrafiltration Rate Data reported here were determined using Bovine Blood diluted to 25% HCT with Bovine Plasma. Blood Flow Rate = 200 mL/min, Dialysate Flow Rate = 0 mL/min, and Transmembrane Pressure = 150 mmHg.
# PERFORMANCE COMPARISONS
CAHP High Performance Cellulose Diacetate Hollow Fiber Dialyzers

<table>
<thead>
<tr>
<th>Model Number</th>
<th>CAHP-170 5M2735</th>
<th>CA-170 5M1735</th>
<th>CAHP-210 5M2736</th>
<th>CA-210 5M1736</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code Number</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure Drop (mmHg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Side</td>
<td>35</td>
<td>35</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Dialysate Side</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Clearances (mL/min)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urea (BUN)</td>
<td>192</td>
<td>188</td>
<td>194</td>
<td>193</td>
</tr>
<tr>
<td>Creatinine</td>
<td>181</td>
<td>167</td>
<td>184</td>
<td>177</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>94</td>
<td>69</td>
<td>106</td>
<td>82</td>
</tr>
<tr>
<td>Ultrafiltration Rate (mL/hr/mmHg)</td>
<td>12.6</td>
<td>8.1</td>
<td>16.4</td>
<td>9.8</td>
</tr>
</tbody>
</table>

Note: Performance Data reported here are *In Vitro* results.

Clearance Data reported here were determined at Transmembrane Pressure = 0 mmHg, Blood Flow Rate = 200 mL/min, and Dialysate Flow Rate = 500 mL/min.

Ultrafiltration Rate Data reported here were determined using Bovine Blood diluted to 25% HCT with Bovine Plasma. Blood Flow Rate = 200 mL/min, Dialysate Flow Rate = 0 mL/min, and Transmembrane Pressure = 150 mmHg.
SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _K030974_

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- [ ] Special 510(k) - Do Sections 1 and 2
- [ ] Abbreviated 510(k) - Do Sections 1, 3 and 4
- [ ] Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

<table>
<thead>
<tr>
<th>Element</th>
<th>Present</th>
<th>Inadequate or Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table of Contents.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Truthful and Accurate Statement.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Device’s Trade Name, Device’s Classification Name and Establishment Registration Number.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Statement of Indications for Use that is on a separate page in the premarket submission.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>510(k) Summary or 510(k) Statement.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Identification of legally marketed predicate device. *</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Class III Certification and Summary. **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (g)]</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>510(k) Kit Certification ***</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Section 2: Required Elements for a SPECIAL 510(k) submission:

<table>
<thead>
<tr>
<th>Required Element</th>
<th>Present</th>
<th>Inadequate or Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and 510(k) number of the sponsor’s own, unmodified predicate device.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>A description of the modified device and a comparison to the sponsor’s predicate device.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor’s unmodified predicate device.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>A statement that the modification has not altered the fundamental technology of the sponsor’s predicate device.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>A Design Control Activities Summary that includes the following elements (a-e):</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>a. 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.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>c. A Declaration of Conformity with design controls that includes the following statements:</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.</td>
<td>✔️</td>
<td></td>
</tr>
</tbody>
</table>
Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

<table>
<thead>
<tr>
<th>Present</th>
<th>Inadequate or Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>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. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)</td>
<td></td>
</tr>
<tr>
<td>For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]</td>
<td></td>
</tr>
<tr>
<td>For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.</td>
<td></td>
</tr>
<tr>
<td>For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.</td>
<td></td>
</tr>
<tr>
<td>For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.</td>
<td></td>
</tr>
<tr>
<td>Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.</td>
<td></td>
</tr>
</tbody>
</table>

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.
Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Present</th>
<th>Inadequate or Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Biocompatibility data for all patient-contacting materials, OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>certification of identical material/formulation:</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>b) Sterilization and expiration dating information:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>i) sterilization process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ii) validation method of sterilization process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>iii) SAI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>iv) packaging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>v) specify pyrogen free</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vi) ETO residues</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vii) radiation dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Software Documentation:</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Items with checks in the “Present but Deficient” column require additional information from the sponsor. Items with checks in the “Missing” column must be submitted before substantive review of the document.

Passed Screening  ✓ Yes ☐ No
Reviewer: ____________________
Concurrence by Review Branch: ____________________
Date: 12/5/23

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html
# Internal Administrative Form

## K030974

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the firm request expedited review?</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>2. Did we grant expedited review?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Have you verified that the Document is labeled Class III for GMP purposes?</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>4. If, not, has POS been notified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Is the product a device?</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>6. Is the device exempt from 510(k) by regulation or policy?</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>7. Is the device subject to review by CDRH?</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>8. Are you aware that this device has been the subject of a previous NSE decision?</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Are you aware of the submitter being the subject of an integrity investigation?</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>11. If, yes, consult the ODE Integrity Officer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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