

APR 15 1999

510K Notification
Althin Medical AB Altracart II
April 6, 1999

SECTION XV.

510(K) Summary

Submitter: Althin Medical AB
Box 39
S-372 21 RONNEBY, Sweden
Phone: 46-457 759 00

Date prepared: 6 April, 1999

Device name: Althin Medical AB Altracart II

Classification name: Hemodialysis Accessories
Hemodialysis Concentrate Solutions & Powders

Predicate device: Gambro BiCart Columns

Device Description:

The Althin Medical AB Altracart II is a column, which contains sodium bicarbonate formulated and intended for use in hemodialysis when mixed or proportioned with the appropriate volume of purified water and acid concentrate solution. It is designed to fit into a holder with a connecting system where a spike punctures a membrane at the top and bottom of the cartridge/column which then permits water to flow through the column and mix with the sodium bicarbonate. The connections to the column are sealed by a standard O-ring, which allows an internal positive or negative pressure to be created in the column. The Altracart II is fitted with a mesh filter to prevent the sodium bicarbonate powder from entering the dialysis machine before it is dissolved or placed in solution with water. The Altracart is supplied in the following 2 configurations:

Altracart II Number	Weight of Sodium Bicarbonate (grams)	Contains a Valve
500-750 A	750	No
500-000 A	1000	No

The different weights of sodium bicarbonate, 750 and 1000 grams are provided in the Altracart II to accommodate dialysis treatment sessions of shorter and longer durations.

This sodium bicarbonate powder when proportioned/ mixed with pre-treated or purified water meeting or exceeding AAMI Standards, may be used in conventional and commercially available hemodialysis machines or monitors to include the Althin System 1000, Tina, Altra Touch machines, and the Cobe Centry 3 hemodialysis machines as a hemodialysis solution.

The Altracart II can be used with all of these machines which have a cartridge holder installed for use with another manufacturer's sodium bicarbonate columns (ie. Gambro BiCart column). Information is provided in 510(k) Notification which demonstrates that the Althin Medical AB Altracart II can be used with these machines and column holders. Included in this 510(k) is also information and a description of the Altracart II holder retrofit kits designed for installation on the Althin System 1000, Tina and Altra Touch hemodialysis machines.

The hemodialysis sodium bicarbonate powder presented in this 510K Notification is intended to be used in three stream hemodialysis machines in which an acidified concentrate is proportioned into one stream, a sodium bicarbonate, concentrate solution which has been prepared by mixing the powder with a specified volume of water is proportioned into the second stream of the hemodialysis machine, and water is proportioned into the third stream. The Altracart II columns are designed to be used with commercially available acid concentrate solutions containing 3 mmol of H^+ (hydrogen) and between 100-103 mmol Na^+ (sodium). The final dialysis solution prepared using the Altracart II will have between 135 and 140 mmol of sodium and 32 to 42 mmol of bicarbonate per liter depending on the acid concentrate and sodium profiling system used with and depending on the particular hemodialysis machine. These three streams are then mixed to prepare a final proportioned hemodialysis solution. These types of a final hemodialysis solutions are commonly referred to as "Bicarbonate Hemodialysis Solutions." These proportioned hemodialysis solutions are then heated to body temperature and then perfused through the dialysis fluid compartment of artificial kidneys or hemodialyzers. These bicarbonate hemodialysis solutions are separated from the patient's blood by means of a semi-permeable cellulosic or non-cellulosic membrane which serves as a molecular weight selective barrier to the passage of molecules beyond a certain molecular weight. The molecular weight cut-off of each type of membrane may vary depending on the membrane type, manufacturing process, etc. The semi-permeable membrane in a hemodialyzer permits the passage of smaller molecular weight (less than 5,000 daltons for conventional cellulosic membranes), ionized and non-ionized molecules, waste products and toxins (i.e. blood urea nitrogen, creatinine, potassium, etc.) contained in the patient's blood circulating through the dialyzer, to pass through the semi-permeable membrane into the bicarbonate hemodialysis solutions, exit the hemodialyzer, enter the hemodialysis monitor and exit the monitor and are ultimately discarded. The ionic and molecular composition of the hemodialysis solution establishes the concentration gradient between the blood and the hemodialysis solution passing through the hemodialyzer which permits the effective removal of waste products and toxins found in excess in the patient's blood during acute and end-stage renal failure.

Since different patients have different requirements for the removal rates and quantities of various molecules and toxins (i.e. blood urea nitrogen, creatinine, potassium, phosphate, magnesium, chloride, sodium calcium water, etc.) in acute and chronic renal failure, it necessitates having a variety of different bicarbonate containing hemodialysis solutions to satisfy the needs of all acute and end-stage renal failure patients. In addition, there a number of different types of hemodialysis machines which have different proportioning rates. The Altracart II which is a column containing sodium bicarbonate and presented in this 510K Notification is designed or formulated to be used with hemodialysis machines that proportion at different ratios.

Predicate Devices:

The Althin Medical AB Altracart II sodium bicarbonate containing columns for hemodialysis are identical in design and construction to the currently marketed Gambro BiCart Columns which has been approved for marketing / sale in the United States under a 510K Notifications (K873155 and K940601). Both the predicate and the proposed devices, incorporate an identical compound, sodium bicarbonate and other dialysis fluid contact materials and have the same intended use, preparation of a hemodialysis solution containing sodium bicarbonate.

Intended Use:

The Althin Medical AB Altracart II is indicated for the preparation of sodium bicarbonate containing hemodialysis solutions for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/ monitor and acid concentrate solutions.

This indication statement is essentially the same as the indication statement for the predicate device.

Technological Characteristics:

Comparing the proposed device to the predicate devices, both devices utilize the same range of chemical compositions, packaging and formulations. There are no significant differences.

Summary of Non-Clinical Tests:

In vitro testing was performed to determine the chemical composition and range of composition. The results of these tests confirmed that the proposed device is substantially equivalent to the proposed device for these parameters.

Clinical Test Results:

Clinical testing was not performed

Conclusions:

Testing performed on the Althin Medical AB Altracart II indicates that they are safe, effective, and perform as well as the predicate device, when used in accordance with the instructions for use.



APR 15 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Ulf Lundgren
Director of Quality Assurance
Althin Medical AB
Box 39 (Fridhems. 15)
372 21 Ronneby
SWEDENRe: K990010
Althin Medical AB Altracart II
Dated: March 30, 1999
Received: April 8, 1999
Regulatory Class: II
21 CFR 876.5820/Procode: 78 KPO

Dear Mr. Lundgren:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

This letter will allow you to 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990010

510K Notification
Althin Medical AB Altracart II
December 22, 1998

SECTION XVIII.

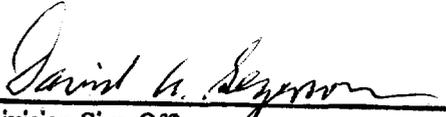
Indications for use Statement

Indications for Use: Althin Medical AB Altracart II

The Althin Medical AB Altracart II is indicated for the preparation of sodium bicarbonate containing hemodialysis solutions for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine / monitor and acid concentrate solutions.

Prescription

Over-the-Counter


David G. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990010/s⁰¹

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