

October 10, 2005

TOTAL WATER TREATMENT SYSTEMS
DOUG MIKELSON
5002 WORLD DIARY DR
MADISON WI 53718

Re: Description: ALTERNATE SYSTEM
Manufacturer: TOTAL WATER TREATMENT SYSTEMS
Product Name: DIALYSIS WATER SYSTEM
Model Number(s): 510K
Product File No: 20050615

The specifications and/or plans for this plumbing product have been reviewed and determined to be in compliance with chapters Comm 82 through 84, Wisconsin Administrative Code, and Chapters 145 and 160, Wisconsin Statutes.

The Department hereby issues an alternate approval to s. Comm 84.30 (4) (e) based on the Wisconsin Statutes and the Wisconsin Administrative Code. This approval is valid until the end of October 2010.

This alternate approval is contingent upon compliance with the following stipulation(s):

- This alternate system approval is limited to a maximum of sixty (60) dialysis stations. The dialysis units themselves must be approved as a health care plumbing appliance as required by s. Comm 84.10
- The alternate system covered by this approval begins at the inlet of the water distribution system which solely serves the 510K systems covered by this approval.
- All piping used within this alternate system shall be installed on cold (i.e less than 85 degrees F) water supplies only.
- This alternate system shall be installed by properly licensed Wisconsin plumber as described in Chapter 145 of Wisconsin State Statute.
- If PVC pipe is used to construct this alternate plumbing system, then the PVC pipe shall conform to ASTM D1785, ASTM D2241 or AWWA C900. The fittings used to join the PVC pipe shall conform to ASTM D2464, ASTM D2466, ASTM D2467, ASTM D3311, ASTM F409, ASTM F1336 or ASTM F1866.
- If CPVC pipe is used to construct this alternate plumbing system, then the CPVC pipe shall conform to ASTM D2846, ASTM F441/F441M or ASTM F442/F442M. The fittings used to join the CPVC pipe shall conform to ASTM F437, ASTM F438 or ASTM F439.
- If polypropylene pipe is used to construct this alternate plumbing system, then the polypropylene pipe shall meet the dimensional tolerances of ASTM D2447 and be fabricated of a resin conforming to ASTM D4101 (Type I or Type II) . The joints used to join the polypropylene pipe shall conform to ASTM D2657.
- If PVDF pipe is used this alternate plumbing system, then the PVDF pipe shall meet the dimensional tolerances of ASTM D2447 and be fabricated of a resin conforming to ASTM D3222. The joints used to join the PVDF pipe shall conform to ASTM D2657.

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- All piping used within this alternate plumbing system shall be supported at four foot intervals in the vertical and horizontal directions.
- All piping shall be labeled with the following minimum information:
 1. The manufacturer's name;
 2. The trade designation;
 3. The type of material;
 4. The maximum working temperature and pressure; and
 5. The mark of the certifying agency.
- This alternate plumbing system is subject to plan review as required by s. Comm 82.20.

If a reduced pressure zone (RPZ) cross connection control device is installed as part of this alternate system, then the RPZ is subject registration and annual testing as required by s. Comm 82.20.
- This alternate system approval pertains only to the alternate piping materials used within the 510K system.

The department is in no way endorsing this product or any advertising, and is not responsible for any situation which may result from its use.

Sincerely,

Glen W. Schlueter
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