



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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510(k) Number (if known): K 970482

Device Name: TRANSCOM COLON HYDROTHERAPY MODEL HC-2000

Indications For Use:

The indication for use of this device must be restricted to colon cleansing when medically indicated, such as before radiological or endoscopic examination.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Rathjens  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K970482

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use