Class 2 Recall RENASYS

See Related Information[22]

Date Posted	October 08, 2014
Recall Status[1]	Open
Recall Number	Z-0040-2015
Recall Event ID	69146[23]
Premarket Notification 510(K) Numbers	K082426[24] K102001[25]
Product Classification	Negative Pressure Wound Therapy Powered Suction Pump[26] - **Product Code** OMP[27]
Product	RENASYS EZ/ RENASYS EZ Plus 800 mL canister with Solidifier Product Usage: RENASYS EZ and RENASYS EZ Plus Canisters are used for the collection of exudate removed from wounds being treated by negative pressure wound therapy (NPWT).
Code Information	Item 66800423 Lot # M400058 & Item 66801066 Lot # M400124
Recalling Firm/ Manufacturer	Smith & Nephew, Inc. 970 Lake Carillon Dr Ste 110 Saint Petersburg, Florida 33716-1130
Manufacturer Reason for Recall	RENASYS EZ Canisters exhibiting visible evidence of deformation of the inlet port on the canister lid.
FDA Determined Cause [2]	DESIGN: Device Design
Action	Smith & Nephew sent an Urgent Medical Device Correction Notice dated July 15, 2014 to all US customers via Federal Express delivery. The letter identified the affected product, problem and actions to be taken. The firm instructed customers to discard the affected product and replace with a new one from an unaffected lot. For questions contact 727-399-3785.
Quantity in Commerce	77,164 = (75,619 (Item 66800423) & 1,545 (Item 66801066))
Distribution	Worldwide Distribution - US Nationwide in the states of FL, NC, CA, MO, MA, TX, NY, OH, CO, VA, IL, NJ, TN, NV, MN including Puerto Rico and countries of Canada, Mexico, Dubai, Argentina, Australia, Colombia, Germany, Hong Kong, Jordon, Malaysia, Thailand, Tunisia, New Zealand, South Africa, Shanghai, Brazil, Saudi Arabia and Lebanon.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = OMP and Original Applicant = SMITH & NEPHEW, INC.[30]

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1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain

Class 2 Recall RENASYS

See Related Information[22]

Date Posted	October 08, 2014
Recall Status[1]	Open
Recall Number	Z-0041-2015
Recall Event ID	69146[23]
Premarket Notification 510(K) Numbers	K082426[24] K102001[25]
Product Classification	Negative Pressure Wound Therapy Powered Suction Pump[26] - **Product Code** OMP[27]
Product	RENASYS EZ/ RENASYS EZ Plus 800 mL canister (w/o CLP) with Solidifier Product Usage: RENASYS EZ and RENASYS EZ Plus Canisters are used for the collection of exudate removed from wounds being treated by negative pressure wound therapy (NPWT).
Code Information	Item 66800912 Lot # M400071
Recalling Firm/ Manufacturer	Smith & Nephew, Inc. 970 Lake Carillon Dr Ste 110 Saint Petersburg, Florida 33716-1130
Manufacturer Reason for Recall	RENASYS EZ Canisters exhibiting visible evidence of deformation of the inlet port on the canister lid.
FDA Determined Cause [2]	DESIGN: Device Design
Action	Smith & Nephew sent an Urgent Medical Device Correction Notice dated July 15, 2014 to all US customers via Federal Express delivery. The letter identified the affected product, problem and actions to be taken. The firm instructed customers to discard the affected product and replace with a new one from an unaffected lot. For questions contact 727-399-3785.
Quantity in Commerce	45,466
Distribution	Worldwide Distribution - US Nationwide in the states of FL, NC, CA, MO, MA, TX, NY, OH, CO, VA, IL, NJ, TN, NV, MN including Puerto Rico and countries of Canada, Mexico, Dubai, Argentina, Australia, Colombia, Germany, Hong Kong, Jordon, Malaysia, Thailand, Tunisia, New Zealand, South Africa, Shanghai, Brazil, Saudi Arabia and Lebanon.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = OMP and Original Applicant = SMITH & NEPHEW, INC.[30]

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Class 2 Recall RENASYS

See Related Information[22]

Date Posted	October 08, 2014
Recall Status[1]	Open
Recall Number	Z-0039-2015
Recall Event ID	69146[23]
Premarket Notification 510(K) Numbers	K082426[24] K102001[25]
Product Classification	Negative Pressure Wound Therapy Powered Suction Pump[26] - **Product Code** OMP[27]
Product	RENASYS EZ/ RENASYS EZ Plus 250 mL canister with Solidifier Product Usage: RENASYS EZ and RENASYS EZ Plus Canisters are used for the collection of exudate removed from wounds being treated by negative pressure wound therapy (NPWT).
Code Information	Item 66800058 Lot # M400021 & Item 66800913 Lot # M400067
Recalling Firm/ Manufacturer	Smith & Nephew, Inc. 970 Lake Carillon Dr Ste 110 Saint Petersburg, Florida 33716-1130
Manufacturer Reason for Recall	RENASYS EZ Canisters exhibiting visible evidence of deformation of the inlet port on the canister lid.
FDA Determined Cause [2]	DESIGN: Device Design
Action	Smith & Nephew sent an Urgent Medical Device Correction Notice dated July 15, 2014 to all US customers via Federal Express delivery. The letter identified the affected product, problem and actions to be taken. The firm instructed customers to discard the affected product and replace with a new one from an unaffected lot. For questions contact 727-399-3785.
Quantity in Commerce	19,499 = (10,849 (Item 66800058) & 8,650 (Item 66800913))
Distribution	Worldwide Distribution - US Nationwide in the states of FL, NC, CA, MO, MA, TX, NY, OH, CO, VA, IL, NJ, TN, NV, MN including Puerto Rico and countries of Canada, Mexico, Dubai, Argentina, Australia, Colombia, Germany, Hong Kong, Jordon, Malaysia, Thailand, Tunisia, New Zealand, South Africa, Shanghai, Brazil, Saudi Arabia and Lebanon.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = OMP and Original Applicant = SMITH & NEPHEW, INC.[30]

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