Class 2 Device Recall RENASYS

Date Posted: October 08, 2014
Recall Status: Open
Recall Number: Z-0040-2015
Recall Event ID: 6914623
Premarket Notification 510(K) Numbers: K08242624 K10200126
Product Classification: Negative Pressure Wound Therapy Powered Suction Pump
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: 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, Jordan, Malaysia, Thailand, Tunisia, New Zealand, South Africa, Shanghai, Brazil, Saudi Arabia and Lebanon.
Total Product Life Cycle: TPLC Device Report

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

Links on this page:

Class 2 Recall

**RENASYS**

Date Posted: October 08, 2014
Recall Status: Open
Recall Number: Z-0041-2015
Recall Event ID: 6914623
Premarket Notification 510(K) Numbers: K08242624, K10200125

**Product Classification:** Negative Pressure Wound Therapy Powered Suction Pump, Product Code OMP

**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:** DESIGN Device Design

**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, Jordan, Malaysia, Thailand, Tunisia, New Zealand, South Africa, Shanghai, Brazil, Saudi Arabia and Lebanon.

**Total Product Life Cycle:** TPLC Device Report

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1. For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55
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.

Links on this page:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/cfres.cfm?id=129971

10/14/2014
**Class 2 Recall RENASYS**

**Date Posted**
October 08, 2014

**Recall Status**
Open

**Recall Number**
Z-0039-2015

**Recall Event ID**
69146221

**Premarket Notification 510(K) Numbers**
K08242624 K10200126

**Product Classification**
Negative Pressure Wound Therapy Powered Suction Pump - Product Code OMP27

**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 Peters, 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**
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, Jordan, Malaysia, Thailand, Tunisia, New Zealand, South Africa, Shanghai, Brazil, Saudi Arabia and Lebanon.

**Total Product Life Cycle**
TPLC Device Report

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.5229
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)is with Product Code = OMP and Original Applicant = SMITH & NEPHEW, INC.30

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Links on this page: