FDA Home³ Medical Devices⁴ Databases⁵

Class 1 Device Recall 10 NBF

510(k)⁷|DeNovo⁸|Registration & Listing⁹|Adverse Events¹⁰|Recalls¹¹|PMA¹²|Classification¹³|Standards¹⁴ CFR Title | Radiation-Emitting

X-Ray

Medsun

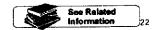
|CLIA¹⁹|TPLC²⁰|Inspections²¹

Assembler¹⁷ Reports¹⁸ Products¹⁶ 21¹⁵

New Search

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Class 1 Recall **10 NRF**



Date Posted

October 09, 2014

Recall Status¹

Open

Recall Number

Z-0014-2015

Recall Event ID

69276²³

Product Classification

Fixative, Formalin-Containing²⁴ - Product Code LDY²⁵

Product

Richard-Allan Scientific 10% Neutral Buffered Formalin. Product Usage: 10% NBF is used to store and fixate tissue prior to grossing and histological examination. It is

a primary fixative that prevents autolysis (degradation) of tissue.

Code Information

Product Code: LC-0060 Lot Number: 300445

Recalling Firm/ Manufacturer

Richard-Allan Scientific Company

4481 Campus Dr

Kalamazoo, Michigan 49008-2590

For Additional Information Contact Sarah Rickert 616-385-4466

Manufacturer Reason for Recall

The affected lots could have NBF concentrations that are lower or higher than the desired

specifications.

FDA Determined

Cause 2

COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Mix-Up of

Materials/Components

Action

The firm issued an "URGENT MEDICAL DEVICE RECALL" letter to all affected customers. The notification identified the affected products, reason for voluntary recall, risk to health, actions to be taken, and instructions to complete the attached Acknowledgement Form. For questions, contact Sarah Rickert at 269-544-5628 or sarah.rickert@thermofisher.com.

Quantity in Commerce

80 cases

Distribution

Worldwide Distribution-USA (nationwide) including the states of PA, IL, CA, TX, GA, WA, MA, KY, OH, NY, VA, NC, IN, NJ, MN, UT, HI, FL, KS, TN, MO, MI, MD, LA, NM, DE, CO,

WV, OR, WI, AZ, SC, IA, and NE and the country of Canada.

Total Product Life Cycle

TPLC Device Report²⁶

Links on this page:

- http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm

¹ For details about termination of a recall see <u>Code of Federal Regulations (CFR) Title 21 §7.55²⁷</u>

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

FDA Home³ Medical Devices⁴ Databases⁵

Class 1 Device Recall 10 NBF

6 510(k)⁷|DeNovo⁸|Registration & Listing⁹|Adverse Events¹⁰|Recalls¹¹|PMA¹²|Classification¹³|Standards¹⁴

CFR Title | Radiation-Emitting 21¹⁵ Products¹⁶

X-Ray Assembler¹⁷ Medsun Reports¹⁸ |CLIA¹⁹|TPLC²⁰|Inspections²¹

New Search

Back to Search Results

Class 1 Recall

See Related Information 22

Date Posted

October 09, 2014

Recall Status¹

Open

Recall Number

Z-0016-2015

Recall Event ID

6927623

Product Classification

Fixative, Formalin-Containing²⁴ - Product Code LDY²⁵

Product

Richard-Allan Scientific 10% Neutral Buffered Formalin. Product Usage: 10% NBF is used to store and fixate tissue prior to grossing and histological examination. It is a primary fixative that provents putalvair (description) of tissue.

a primary fixative that prevents autolysis (degradation) of tissue.

Code Information

Product Code: 51401 Lot Number: 300649

Recalling Firm/ Manufacturer Richard-Allan Scientific Company

4481 Campus Dr

Kalamazoo, Michigan 49008-2590

For Additional Information Contact

Sarah Rickert 616-385-4466

Manufacturer Reason

for Recall

The affected lots could have NBF concentrations that are lower or higher than the desired

specifications.

FDA Determined

Cause 2

COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Mix-Up of

Materials/Components

Action

The firm issued an "URGENT MEDICAL DEVICE RECALL" letter to all affected customers. The notification identified the affected products, reason for voluntary recall, risk to health, actions to be taken, and instructions to complete the attached Acknowledgement Form. For questions, contact Sarah Rickert at 269-544-5628 or sarah.rickert@thermofisher.com.

Quantity in Commerce

199 cases

Distribution

Worldwide Distribution-USA (nationwide) including the states of PA, IL, CA, TX, GA, WA, MA, KY, OH, NY, VA, NC, IN, NJ, MN, UT, HI, FL, KS, TN, MO, MI, MD, LA, NM, DE, CO,

WV, OR, WI, AZ, SC, IA, and NE and the country of Canada.

Total Product Life Cycle

TPLC Device Report²⁶

Links on this page:

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