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1 Submitter:

Themo Electron LED GmbH (a subsidiary of Thermo Fisher Scientific Inc.)
Am Kalkberg,
37520 Osterode
Phone: +49 5522 316 200
Fax: +49 5522 316 225
FDA Registration Number: 8010672

Contact Person:

Abdullah Laaboubi
Regulatory Affairs / Compliance R&D
Am Kalkberg
37520 Osterode am Harz
Germany
Phone: +49 5522 316 162
Fax: +49 5522 316 225
abdullah.laaboubi@thermofisher.com

Owner/Operator:

THERMO FISHER SCIENTIFIC INC.6
236 perinton parkway
fairport, NY 14450
FDA Owner/Operator Number: 21827737

Official correspondent:

Marilyn Barry
THERMO FISHER SCIENTIFIC
275 aiken rd.
asheville, NC 28804
Phone: 828-6584400

US Agent:

Marilyn Barry
THERMO FISHER SCIENTIFIC
275 aiken rd.
asheville , NC 28804
Phone: 828 6584400 ext
Email: marilyn.barry@thermofisher.com

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2 Device Information

Device name:	CW3 Cell Washer
Brand/Proprietary Name:	Thermo Scientific
Common/Usual Name:	Cell Washer
Classification Name:	centrifuge, cell-washing, automated for immuno-hematology
Regulation Description:	Automated cell-washing centrifuge for hematology.
Product Code:	KSN
Regulation Number:	864.9285
Device Class:	2

3 Predicate Device

510(k) Number:	BK820020 IEC Centra-W Cell Washer
Device Name	Automated Cell-Washing Centrifuges for immuno-
Original Applicant	International Equipment Company, 300 second avenue, needham heights, MA 02194

Comment to predicate device:

The predicate device was developed and manufactured by International Equipment Company (IEC). IEC was merged by Thermo Fisher Scientific and the FDA file was transferred to Thermo Fisher Scientific Asheville (a subsidiary of Thermo Fisher Scientific Inc.).
The IEC Centra-W Cell Washer was renamed to the Thermo Scientific Blood Cell Washing System Centra W (80300568, 80300569) and the Sorvall Blood Cell Washing System CW2 and CW2 Plus (80300566, 80300567).
For detail Informations see Registered Establishment Number: 1036832 / Owner/Operator Number 2182773.
The new CW3 Cell Washer is an Update of the Centra W and CW2 Plus.

4 Device Description:

Intended use

The Thermo Scientific CW3 cell washer is designed to perform cell washing in multiple washing cycles using saline solution. The cell washer provides blood cells after sample separation, which can be used for further blood testing such as anti-globulin test, ABO compatibility, Rh testing, cross matching and anti body screening.

The centrifuge should always be operated by a trained individual such as a clinical laboratory technologist or a person with a similar education.

Indications for use

The Thermo Scientific CW3 cell washer is designed to perform cell washing in multiple washing cycles using saline solution.

The cell washer provides blood cells after sample separation, which can be used for further blood testing such as anti-globulin test, ABO compatibility, Rh testing, cross matching and anti body screening.

The anti-globulin reaction, ABO compatibility, Rh testing, cross matching procedures are used to check the transfusion reactions of patient.

The intended use of the CW3 cell washer is to provide accurate separated blood cells.

The testing procedures provided by different reagent manufacturers of anti-globulin test, ABO compatibility, Rh testing, cross matching and anti body screening. The procedures of reagent manufacture needs to be follow.

Function

The CW3 cell washer is a tabletop instrument that separates and washes blood cells trough several operation sequences with saline solution. A part of the instrument is a 12- or 24 place rotor with a distributor on the top. The rotor can load with 10 or 12 ml standard glass tubes. The instrument is designed for automatically and manual repeatable standard procedures in routine labs and routine blood banks.

The operation sequences are shown in the graphic below:

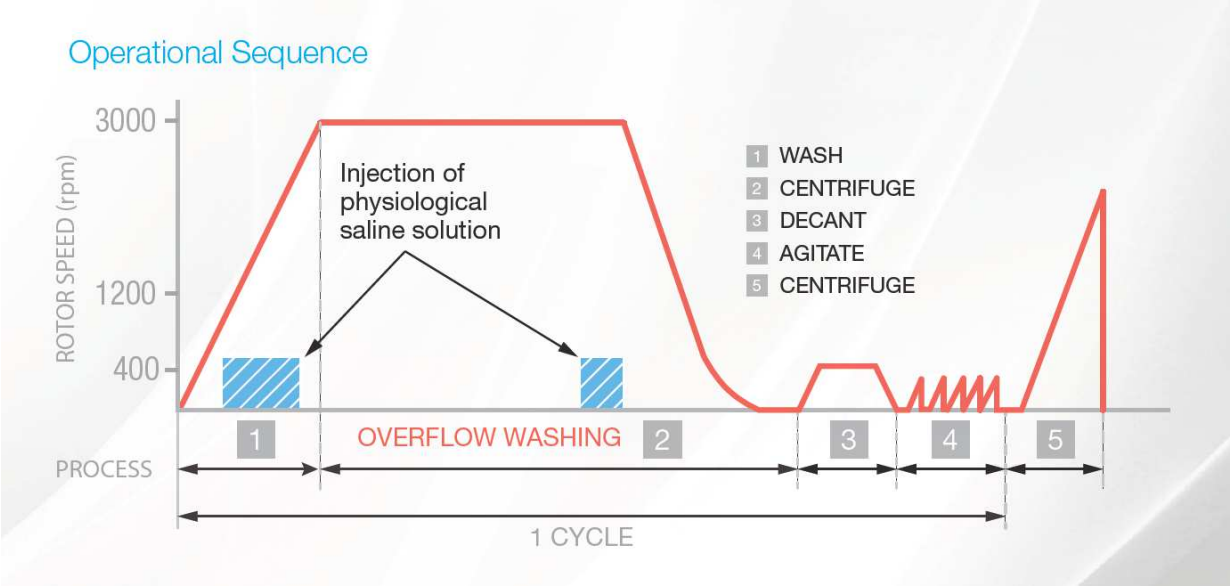

figure 1: operation sequences of the CW3 cell washer

Each cycle needs a washing, centrifugation, decanting and agitation step.
The washing cycles can choose between 1- 9 by the user, depending from the standard procedure of the lab. The factory setting of the 3 cycles represent the common setting.
The centrifugation and agitation time, as well as centrifugation and decantation speed are operator-programmable.

Step 1: In the washing step a fixed amount of saline is pumped into the distributor. By centrifugal force, the saline is jetted from the distributor into test tubes. At that time, blood cells in each test tube are sufficiently suspended in the saline.

Step 2-3: During the centrifugation and decanting step blood cells are centrifuged and only the saline is decanted from the test tubes and the blood cells remain.

Step 4: The agitation step provides re-suspension of cells and spins the cells before cycle completion.

Step5: This centrifugation step is performed at the end of the washing procedures. The rotor spins about 5 seconds to collect the blood cells adhered to the wall surfaces of the test tubes at the bottom. This is done to ensure the reaction with the Coombs reagent.

5 Substantial Equivalence Comparison

Predicate device: CW2 Plus Cell Washer	New Device: CW3 Cell Washer
Intended use	
User manual: The CW2 Plus is a bench top Cell Washer that automatically performs the washing phase of the anti-globulin procedure in tests using up to six drops of blood sample. Brochure: This advanced, easy-to-use instrument simplifies work and reduces time required to wash blood cells for antiglobulin reagent tests such as ABO compatibility, Rh testing, cross matching and the Coombs procedure.	User Manual: The Thermo Scientific CW3 cell washer is designed to perform cell washing in multiple washing cycles using saline solution. The cell washer provides blood cells after sample separation, which can be used for further blood testing such as antiglobulin test, ABO compatibility, Rh testing, cross matching and anti body screening. The centrifuge should always be operated by a trained individual such as a clinical laboratory technologist or a person with a similar education. Brochure: Applications Anti-globulin tests, ABO compatibility, Rh testing, cross matching and anti body screening.
Explanation to intended use	
The antiglobulin test also known as Coombs test and it includes different procedures like: - ABO compatibility - Rh testing - cross matching The test is used to screen for antibodies in the preparation of blood for blood transfusion. The donor's and recipient's blood have to be ABO and Rh D compatible. The indirect Coombs test is used to test a sample of the recipient's serum for antibodies against a sample of the blood donor's RBCs. This is sometimes called cross-matching blood.	There are no changes to the intended use of the CW3 from that of the predecessor Cell Washer. The amount of blood is defined by the own operation procedures of the different labs.

Users / environment/ working places	
Hospital Clinical Laboratories, Routine Laboratories, blood bank Users: A trained specialist like medical laboratory technician or a person with a similar education.	Hospital Clinical Laboratories, Routine Laboratories, blood bank Users: A trained specialist like medical laboratory technician or a person with a similar education.

table 1: differences of intended use of the devices

There are no signification differences between and the predicate device and CW3, which raises additional questions resulting to the safety and effectiveness of the device.

6 Comparison of the technological characteristics with the predicate device

	CW3 New Device	**CW2 PLUS Predicate Device**
Rotor	metal	plastic
The max. number of test tubes placed in the rotor:	24 or 12	12
Size of test tubes: Diameter length	12 mm/10 mm (diameter) 75 mm (length)	12 mm/10 mm (diameter), 75 mm (length)
Tank for saline solution	Yes	No
Easy removable drain cover	Yes	No
Easy removable inner chamber	Yes	Yes
Number of process cycles	1 to 9	1 to 4
Cycle setting switch	60 seconds (auto centrifugation time 35 seconds)	80 seconds (auto centrifugation time 41 seconds)
AUTO CENTRI TIME setting switch	99 seconds (max)	No, only 41 seconds
MANUAL CENTRI TIME switch	999 seconds (max)	999 seconds (max)
MANUAL SPEED setting switch	1200 or 3000 rpm	No, only 3400 – 3500 rpm
DECANT Speed setting switch[a]	350 to 500 rpm	No, only 550 – 600 rpm
OVER FLOW setting switch[b]	Yes	No
PROGRAM button[c]	3 options	No
AGITATE TIME setting switch[d]	Yes (0 -99)	No
MELODY setting switch	5 melodies or electronic buzzer	Only electronic buzzer
PROCESS LED[e]	Yes	No, only CHECK button[g]
Hold button[f]	No	Yes
Dimension [mm]	370 (W)×450 (D)×410 (H)	321 x 435 x 386
Weight [kg]	28	17.8

table 2: device comparison

Discussion of the device comparison

Both units are used to perform cell-washing procedures. A fixed amount of saline is pumped through the distributor into the test tubes. During the centrifugation and decanting step cells are centrifuged and saline is decanted. The agitation step provides re-suspension of cells.
A Gap analysis to predicate device was performed the detail can be found in substantial discussion. No substantial differences were found.
The new device CW3 and the predicate device CW2 Plus have both the same structure. Both units consist of a centrifugation chamber including a drain cover, nozzle, a rotor, distributor, peristaltic pump and a control panel.
Due to the fact that the new device was developed to create a broadening and improvement of the predicate device, there are some differences between these two units. These differences are detailed in table 1 above, none of these differences constitute a technological differences that are for improvement to functions only. The proposed device has similar design and technological characteristics as the predicate devices named Sorvall Blood Cell Washing System CW2 Plus.

7 Tests and standards

Numerous types of testing were performed for CW3 Cell Washer.
The table below shows the test standards and there results.

Standards:	Tested by	Result
UL Std. No. 61010-1 (2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements	Canadian Standards Association (CSA)	**Pass**
IEC 61010-2-020:2006 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2-020: Particular requirements for laboratory centrifuges	Canadian Standards Association (CSA)	**Pass**
EN 61326-1 EMC standard for measurement, control and laboratory National Regulation of Federal Communications Commission (FCC) Part 15	Underwrite Laboratories (UL) Japan, Inc. Kashima EMC Lab	**Pass**
ISO 14971:2012 medical devices - application of risk management to medical devices. FDA Recognition Number: 5-40 and 5-41	Thermo Electron LED GmbH	**Pass**
ISO 15223-1 Second Edition 2012-07-01, medical devices - symbols to be used with medical device labels, labelling, and information to be supplied - part 1: general requirements. FDA Recognition Number:5-90	Thermo Electron LED GmbH	**Pass**
EN ISO 18113-1:2011, EN ISO 18113-3:2011In vitro diagnostics medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic	Thermo Electron LED GmbH	**Pass**

instruments for professional use (ISO 18113-3:2009).		
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005	Thermo Electron LED GmbH	**Pass**
Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design, Document issued on: June 22, 2011	Thermo Electron LED GmbH	**Pass**
Shipping testing (a part of IEC 61010-2-101)	Thermo Electron LED GmbH	**Pass**

table 3: tests and standards

8 Validation and Performance Testing

Numerous types of testing were performed for CW3 Cell Washer.
The table below shows the test standards and there results.

	Tested by	Result
Validation Test by Wake Forest Baptist Health Winston –Salem, NC 27157.	WFBH Blood bank Wake Forest Baptist Health Winston –Salem, NC 27157	**Pass**
WFBH Blood bank performed correlation studies with their current method of cell washing as part of the validation of CW3 Cell washer		
Validation of the application by Diakonie-Klinikum Rothenburg Germany.	Diakonie-Klinikum Rothenburg Germany	**Pass**
The purpose of testing is to imitate customers handling of the CW3 Cell Washer and to test the unit under conditions that will reflect common laboratory applications/usage. To facilitate comparison, blood cell procedures were also performed using a routine device of the lab.		
Validation of the instrument by Thermo Fisher Scientific Osterode am Harz, Germany	Thermo Electron LED GmbH	**Pass**
The purpose of testing was to imitate customers handling of the Thermo Scientific CW3 Cell Washer and to determine if it is ready for use by customers. The evaluation was conducted to validate the device conforms user needs and intended use. Testing evaluated the system performance using customer- like scenarios.		
Gap Analysis	Thermo Electron LED GmbH	**Pass**
A Gap analysis was performed to predicate device to improve the new device. Details can be found in substantial discussion.		

table 4: validation tests

9 Conclusion

The successful testing demonstrates the safety and effectiveness of the modified CW3 when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.