# Project Description

**Title:** Current part, Hubbel GFRST15W is discontinued.

**Description:** Current part, Hubbel GFRST15W is discontinued, Replace part with the Hubbel

GFR15W.

# Product Family and Models Affected

**Affected Product Family:** HPLRF, Chromatography Units

**Affected Product Models:**

|  |  |  |  |
| --- | --- | --- | --- |
| TSX2305CA | TSX3005CA | TSX4505CA | TSX5005CA |
| TSX2305CD | TSX3005CD | TSX4505CD | TSX5005CD |
| TSX2305CY | TSX3005CV | TSX4505CY | TSX5005CY |
| TSX2305CZ | TSX3005CY | TSX4505CZ | TSX5005CZ |
| CH2305CA | CH3005CA | CH4505CA | CH5005CA |
| TSG2305CA | TSG3005CA | TSG4505CA | TSG5005CA |

# Country(s)/Region(s) in scope

North America, EMEA

# Regulatory status of the product

|  |  |  |
| --- | --- | --- |
| S. No | Description | Applicability |
| 1.0 | Medical: | Yes |
| 1.1 | Countries of Registration: | South Africa (SAHPRA) |
| 1.2 | List the classification by country | NA |
| 2.0 | Non-Medical | Yes |
| 3.0 | Certifications/markings on the units: | UL, CE, cUL |

# Regulatory Review Details

* **List Regulations/Directives/Standards affected by this change (if any)**
  + **Regulations / Directives Applicable**
    - There are no Regulations and Directives affected due to this change.
  + **Standards Applicable**
    - There are no standard requirements affected due to this change.
* **Documentation Requirements**
  + Design/Manufacturing/Quality
    - Update drawing for the said change. No change in TFS Part number.
    - TSG models will be taken care by NPD (EPD-004342) team.
  + Regulatory
    - REACH, ROHS and Prop65 complaint statement provided.
* **Testing Requirements**
  + Performance
    - Kindly refer PVP, DVR V-000150 and ENG055 testing details and results.
  + Regulatory
    - Hubbel did internal design changes to their part and to differentiate old to new manufacturer part number changed from GFRST15W to GFR15W.
    - Hubbel feedback on old GFCI to new GFCI part changes:

“The two devices have the same function and similar, for and fit.

The two major differences are that the new GFR- series has enhanced electronics that offers superior resistance to nuisance trips caused by harmonics generated on the neutral, and instead of two separate red and green LED's, the new GFR- series offers one multi-colored LED that offers the same indications.”

* + - This is a drop-in replacement the proposed part (GFR15W) has similar or better specs than the current part (GFRST15W).
    - For TFS PN# 49171H03, MFR PN# GFRST15W. No safety file update required for UL file no. E473332-D1017, SA5215 sec.27.
    - No EMI/EMC report updated needed as well.
    - As per approved test plan, all tests completed, and new part passed. All test results reviewed and approved by Tech pulse, Refer DVR document for test results.
    - FAI: both GFCI and manual updates passed FAI
* **Any Specific Medical Device related requirement?**
  + NA

# Regulatory / Agency Documents

|  |  |  |
| --- | --- | --- |
| Document Type | Report Number (if file update is applicable/ NA) | Status (Completed/In-progress) |
| Safety | No | NA |
| EMC | No | NA |
| Wireless | No | NA |
| Medical Device Documents | No | NA |

## Environmental Declarations

|  |  |  |
| --- | --- | --- |
| Document Type | Applicability (Yes/No) | Status (Received/To be provided) |
| ROHS | Yes | Received |
| REACH | Yes | Received |
| Prop65 | Yes | Received |

## Agency Reporting for medical devices

* Did you inform regional RA about the design change?
  + - Yes
* If yes, enter the name of the regional RA
  + - Sabine Hellyer (South Africa)

# Regulatory Affairs Recommendation

* + Based on the above assessment we would recommend approving Verification phase and move to Implementation phase.

# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Number** | **Phase Gate/Description of Change** | **Author** | **Revision Date** |
| 01.00 | Define and Plan Phase RA Approval request | Akanksha F. | 06 June 2024 |
| 02.00 | Verify Phase RA Approval request | Akanksha F. | 13 November 2024 |