

CHF SOLUTIONS, INC.

FORM SD (Specialized Disclosure Report)

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Address	12988 VALLEY VIEW ROAD EDEN PRAIRIE, MN 55344
Telephone	952-345-4200
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM SD

Specialized Disclosure Report

CHF SOLUTIONS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-35312
(Commission File Number)

No. 68-0533453
(I.R.S. Employer
Identification Number)

12988 Valley View Road, Eden Prairie, MN 55344
(Address of principal executive offices)(Zip code)

Gordon Weber (952) 345-4200
(Name and telephone number, including area code, of person to contact in connection with this report)

Check the appropriate box to indicate the rule pursuant to which this form is being filed, and provide the period to which the information in this form applies:

Rule 13p-1 under the Securities Exchange Act (17 CFR 240.13p-1) for the reporting period from January 1 to December 31, 2016.

Section 1 - Conflict Minerals Disclosure

Item 1.01 Conflict Minerals Disclosure and Report

This Form SD of CHF Solutions, Inc. (f/k/a Sunshine Heart, Inc.) (the **“Company”**) is filed pursuant to Rule 13p-1 promulgated under the Securities Exchange Act of 1934, as amended, for the reporting period January 1, 2016 to December 31, 2016.

A copy of the Company’s Conflict Minerals Report is provided as Exhibit 1.01 to this Form SD, and is publicly available in the Investor section of the Company’s website at www.chf-solutions.com, by selecting Financials and Filings under the Investors tab.

Item 1.02 Exhibit

A copy of the Company’s Conflict Minerals Report is provided as Exhibit 1.01 to this Form SD and incorporated herein by reference.

Section 2 - Exhibits

Item 2.01 Exhibits

The following exhibit is filed as part of this report.

<u>Exhibit</u>	<u>Description</u>
1.01	Conflict Minerals Report of CHF Solutions, Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the duly authorized undersigned.

CHF SOLUTIONS, INC.

By: /s/ Claudia Drayton
Claudia Drayton
Chief Financial Officer

May 30, 2017
(Date)

Exhibit List

Exhibit	Description
1.01	Conflict Minerals Report of CHF Solutions, Inc.

CHF SOLUTIONS, INC.
Conflict Minerals Report

For the reporting period from January 1, 2016 to December 31, 2016

Background

This Conflict Minerals Report (the “**Report**”) of CHF Solutions, Inc. (f/k/a Sunshine Heart, Inc.) (“**we**”, “**us**” or the “**Company**”) has been prepared pursuant to Rule 13p-1 and Form SD (the “**Rule**”) promulgated under the Securities Exchange Act of 1934, as amended, for the reporting period January 1, 2016 to December 31, 2016.

The Rule imposes certain reporting obligations on companies who manufacture or contract to manufacture products containing certain specified minerals that are necessary to the functionality or production of the Company’s products. The specified minerals, which we collectively refer to in this Report as the “**Conflict Minerals**,” are gold, columbite-tantalite (coltan), cassiterite and wolframite, including their derivatives, which are limited to tantalum, tin and tungsten. The “**Covered Countries**” for the purposes of the Rule and this Report are the Democratic Republic of the Congo, the Republic of the Congo, the Central African Republic, South Sudan, Uganda, Rwanda, Burundi, Tanzania, Zambia and Angola.

This Report relates to the process undertaken by the Company for the Company’s products that contain Conflict Minerals and were manufactured, or contracted to be manufactured, during calendar year 2016.

Company Overview

We are an early-stage medical device company focused on commercializing the Aquadex FlexFlow® System (the “**Aquadex System**”). The Aquadex System is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. In August 2016, we acquired the Aquadex business from a subsidiary of Baxter International, Inc., a global leader in the hospital products and dialysis markets (“**Baxter**”). The Aquadex FlexFlow consists of: (i) a console, a piece of capital equipment containing electromechanical pumps and an LCD screen (the “**Console**”), (ii) a one-time disposable blood set (the “**Aquadex Blood Set**”), an integrated collection of tubing, filter, sensors, and connectors that contain and deliver the blood from and back to the patient, and (iii) a disposable catheter (the “**Aquadex Catheter**”), a small, dual-lumen catheter designed to access the peripheral venous system of the patient and to simultaneously withdraw blood and return filtered blood to the patient. We are party to a commercial manufacturing and supply agreement with Baxter which requires Baxter to manufacture Aquadex Blood Sets and Aquadex Catheters for a period of 18 months following our acquisition of the Aquadex business. There is no such agreement relating to the manufacturing of Consoles, and we did not manufacture or contract to manufacture any Consoles in calendar year 2016.

Prior to July 2016, we were focused on developing, manufacturing and commercializing the C-Pulse® Heart Assist System (the “**C-Pulse System**”) for treatment of Class III and ambulatory Class IV heart failure. The C-Pulse System utilized the known concept of counterpulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. In March 2016, we announced that we were no longer enrolling patients into our two clinical studies for the C-Pulse System and that we planned to pursue a new strategic direction. In July 2016, we announced that we were moving forward with a therapeutic strategy utilizing neuromodulation rather than counterpulsation. On September 29, 2016, we announced a strategic refocus of our near-term strategy that includes halting clinical evaluations of our neuromodulation technology to fully focus our resources on our recently acquired Aquadex business. During calendar year 2016 while we still contracted for the manufacture and assembling the C-Pulse System, the critical components of the C-Pulse System, including the balloon, driver unit and interface lead, were manufactured and provided by outside suppliers. The testing of these components and assembly of the balloon and cuff, along with the related marking and packaging operations, were done by us in our Eden Prairie, Minnesota facility.

In 2016, the Company’s suppliers for the C-Pulse System include large and small U.S.-based manufacturers of medical device components. Baxter was the only supplier to the Company for the Aquadex System in 2016. Conflict Minerals are necessary to the functionality or production of certain critical components of each of the C-Pulse System and the Aquadex System (the “**Covered Products**”) that were manufactured, or contracted to be manufactured, by the Company during calendar year 2016.

The Company’s Due Diligence Process

The Company formed a cross-functional team to address Conflict Minerals in the supply chain for the C-Pulse System and the Aquadex System. This team included our Facilities Coordinator, Senior Vice President, Research and Development, and Chief Financial Officer. This team conducted a good faith reasonable country of origin inquiry (“**RCOI**”) to identify and trace Conflict Minerals in the Company’s supply chain, using procedures and tools recommended or provided by the Conflict-Free Sourcing Initiative and the Organisation for Economic Cooperation

and Development Due Diligence Guidance for Responsible Supply Chain of Minerals from Conflict-Affected and High Risk Areas: Third Edition, including the related supplements on gold, tin, tantalum and tungsten (the “*OECD Guidance*”).

This RCOI was reasonably designed to determine whether any of the Conflict Minerals originated in the Covered Countries and whether any of the Conflict Minerals may be from recycled or scrap sources. The Company does not purchase Conflict Minerals directly from mines, smelters or refiners; rather the Company contracts to manufacture products from materials and compounds acquired from third parties. The supply chain for the Covered Products is complex, and there are many third parties in the supply chain between the ultimate manufacturer of the Covered Products and the original sources of Conflict Minerals. Therefore, the Company must rely, and has relied, on its suppliers to provide information in their responses to the Company’s inquiries regarding the existence of Conflict Minerals in any materials or products supplied to the Company and the source of such Conflict Minerals, if any. The Company’s direct suppliers are similarly reliant upon information provided by their suppliers. Our measures can provide only reasonable, not absolute, assurance regarding the source and chain of custody of the necessary Conflict Minerals.

The Company determined that five suppliers were within the scope of the Company’s RCOI during calendar year 2016 and contacted all five suppliers, requesting that such suppliers provide Conflict Minerals data by completing the Conflict Mineral Reporting Template, a supply chain survey tool provided by the Conflict-Free Sourcing Initiative (the “*Conflict Mineral Disclosure Form*”). Four out of five suppliers provided responses to the request for information.

In early 2017, the Company’s cross-functional team reviewed the completed Conflict Mineral Disclosure Forms and other correspondence addressing the Company’s requests (the “*Supplier Responses*”). Four of our five suppliers provided responses to our request for information. We did not receive a Conflict Mineral Disclosure Form from our supplier of Driver-Lead Assembly for the C-Pulse System. Requests for additional information were undertaken, as appropriate, and members of the cross-functional team reviewed the final Supplier Responses in April and May 2017. The Company also checked any smelters identified in the Supplier Responses against the lists of certified conflict-free smelters on the Conflict-Free Smelter Program’s website.

Results of Due Diligence Process

Of the Supplier Responses, two suppliers confirmed that no Conflict Minerals contained in the components supplied to the Company are sourced from a Covered Country. The supplier of assembly and packaging for the C-Pulse System’s driver responded that it is not able to determine whether any of the Conflict Minerals in the supplied electronic components originate from a Covered Country as it received responses from very few of its suppliers and was not able to identify any smelters.

Baxter, the Company’s supplier of the Aquadex Blood Set and Aquadex Catheter, responded that it was unable to confirm that the gold contained in components it supplied to the Company and/or other third parties during calendar year 2016 did not originate from a Covered Country. While all of the smelters or refiners of the gold identified by this direct supplier are recognized as conflict free by the Conflict-Free Smelter Program, this supplier received limited or incomplete responses from its suppliers.

The Company had follow-up correspondence and conversations with the direct suppliers that were unable to provide complete responses, but they were unable to provide any additional information to assist the Company in its efforts to identify and trace Conflict Minerals in its supply chain. Therefore, the Company is unable to determine the facilities used to process or the country of origin of all of the necessary Conflict Minerals in the products provided by these two direct suppliers. The Company does not believe it has significant leverage with its existing suppliers, given the minimal amount of purchases relative to the size of the suppliers, to have an impact on the purchasing and sourcing decisions of its suppliers.

Further Efforts

The Company has yet to adopt a formal policy relating to the Conflict Minerals that incorporates the standards set forth in the OECD Guidance, although it has implemented certain provisions in practice. The Company generally is committed to the responsible sourcing of materials of its products and supports greater transparency with regard to its supply chain but is taking a reasonable, measured approach in responding to the requirements of the Rule.

The Company expects to take the following steps, among others, to improve its due diligence measures and to further mitigate the risk that the necessary Conflict Minerals contained in the Company’s products finance or benefit armed groups in the Covered Countries: (i) continuing to identify any products that the Company manufactures or contracts to manufacture that contain Conflict Minerals; (ii) continuing to engage with suppliers to obtain current, accurate and complete information about the supply chain; and (iii) following up appropriately when information provided by suppliers appears to be incomplete or inaccurate. As noted above, the Company’s efforts and impact are limited due to its minimal purchasing relative to the size of its suppliers.
