UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM SD

Specialized Disclosure Report

Helius Medical Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-38445	36-4787690
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

642 Newtown Yardley Road, Suite 100 Newtown, PA (Address of principal executive offices)	18940 (Zip Code)

Dane C. Andreeff, President and Chief Executive Officer, (215) 944-6100
(Name and telephone number, including area code, of the 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, 2022.

Section 1 - Conflict Minerals Disclosure

Item 1.01 Conflict Minerals Disclosure and Report

This Form SD of Helius Medical Technologies, 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 to December 31, 2022.

A copy of the Company's Conflict Minerals Report is filed as Exhibit 1.01 to this Form SD and is publicly available at:

https://heliusmedical.com/index.php/investor-relations/sec-filings.

Item 1.02 Exhibit

A Conflict Minerals Report required by Item 1.01 covering the period January 1 to December 31, 2022 has been filed as Exhibit 1.01 to this Form SD.

Item 2.01 Resource Extraction Issuer Disclosure and Report

Not applicable.

Item 3.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
1.01	Helius Medical Technologies, Inc. Conflict Minerals Report as required by Items 1.01 and 1.02 of Form SD.

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.

Date: May 30, 2023

HELIUS MEDICAL TECHNOLOGIES, INC

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer and Treasurer

Exhibit 1.01

Helius Medical Technologies, Inc.
Conflict Minerals Report
For Calendar Year 2022

Helius Medical Technologies, Inc. ("Helius," the "Company," "we" and "our") submits this Conflict Minerals Report for the period January 1 to December 31, 2022 pursuant to Rule 13p-1 under the Securities Exchange Act of 1934, as amended (the "Rule"). The Rule was adopted by the Securities and Exchange Commission (the "SEC") to implement reporting and disclosure requirements related to conflict minerals as directed by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. The Rule imposes certain reporting obligations on SEC registrants whose manufactured products or products contracted to be manufactured contain conflict minerals which are necessary to the functionality or production of their products. Conflict Minerals are defined as cassiterite, columbite-tantalite, wolframite and gold, including their derivatives, which are limited to tin, tantalum and tungsten (collectively, "3TG").

Overview

Helius's Business

We are a neurotech company in the medical device field focused on neurological deficits using non-implantable platform technologies that amplify the brain's ability to compensate and promote neuroplasticity, improving the lives of people dealing with neurologic diseases. Our first product, known as the Portable Neuromodulation Stimulator ("PoNSTM"), is an innovative non-surgical medical device, inclusive of a controller and mouthpiece, which delivers electrical stimulation to the surface of the tongue to improve balance and gait. The PoNS device is indicated for use in the United States as a short-term treatment of gait deficit due to mild-to-moderate symptoms from multiple sclerosis ("MS") and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

PoNS is also authorized for sale in Canada for three indications: (i) PoNS is authorized as a short-term treatment (14 weeks) of chronic balance deficit due to mild-to-moderate traumatic brain injury and is to be used in conjunction with physical therapy; (ii) PoNS is authorized for use as a short term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from MS and is to be used in conjunction with physical therapy; and (iii) for use as a short-term treatment (14 weeks) of gait deficit due to mild and moderate symptoms from stroke, to be used in conjunction with physical therapy. PoNS is also authorized for sale in Australia for short term use by healthcare professionals as an adjunct to a therapeutic exercise program to improve balance and gait.

The PoNS device has been manufactured by our contract manufacturing partner, a leading, international electronics manufacturer, who manufactured PoNS devices for engineering and design verification testing and for FDA submission as well as commercial devices for launch inventory for commercialization in the United States and Canada.

Helius's Product Covered by this Report

The Company has determined that 3TG is necessary to the functionality or production of the PoNS device, including in the 143 gold-plated electrodes on the mouthpiece, which send mild electrical signals to the tongue.

Accordingly, the Company conducted in good faith a reasonable country of origin inquiry ("RCOI") to determine whether any 3TG contained in the PoNS device originated in the Democratic Republic of the Congo, the Republic of the Congo, the Central African Republic, South Sudan, Uganda, Rwanda, Burundi, Tanzania, Zambia and Angola (together, the "Covered Countries"), or were from recycled or scrap sources.

Reasonable Country of Origin Inquiry

We rely on our sole manufacturer to manufacture the PoNS device. Our sole manufacturer relies on suppliers who supply components and materials for multiple products it manufactures. We do not have direct relationships with any of these suppliers.

Given our position in the supply chain as a “downstream” company, the Company has to rely on its sole manufacturer to conduct its own survey of its “upstream” supply chain in relation to the conflict minerals used in its products. This inquiry consisted of obtaining a written assurance from the Company’s sole manufacturer that it had performed in good faith its own RCOI. Accordingly, we requested and received from the manufacturer a completed Conflict Minerals Reporting Template (“CMRT”). The CMRT included results from our manufacturer’s own diligence process, in which the manufacturer conducted its own supply chain survey and collected CMRTs from its suppliers. However, our manufacturer’s CMRT covered all products manufactured by our supplier, both for the Company and for other customers, and our supplier confirmed, after we followed-up, that it was not able to respond to the CMRT with responses specific to us or the PoNS device.

Due Diligence Performed

Step 1: Establish Strong Company Management Systems

The Company uses the CMRT from the Responsible Minerals Initiative (RMI) to determine the source and chain of custody of 3TG in our supply chain. We reviewed the CMRT sent to us by our sole manufacturer, which was based on responses submitted to our sole manufacturer by its own suppliers.

Step 2: Identify and Assess Risk in the Supply Chain

We requested and received the CMRT received from our sole manufacturer in order to gather information on our supply chain, including whether any of the minerals that could potentially be classified as 3TG are contained in materials supplied to our manufacturer or came from recycled or scrap sources and whether those minerals originated from the Covered Countries.

We reviewed our sole manufacturer’s CMRT for completeness and consistency of answers. The CMRT we received from our manufacturer showed that the manufacturer received completed CMRT responses from less than 50% of the suppliers surveyed.

Because our manufacturer is only able to provide a CMRT that was company-wide and not specific to us or the PoNS device, the information we received reports 3TG data for all products manufactured by our sole manufacturer. Accordingly, we are not able to determine whether the smelters and refiners identified by our manufacturer actually processed the 3TG in the PoNS device. Given the large number of identified smelters and refiners, the relative size of our operations compared to our manufacturer and the limited number of PoNS devices we have contracted to manufacture to date, we believe that the smelter and refiner list provided is significantly over-inclusive and that we do not have sufficient information to reasonably identify smelters or refiners that processed the 3TG contained in the PoNS device. Accordingly, do not have enough information to fully assess risks in our supply chain.

Step 3: Design and Implement a Strategy to Respond to Identified Risks

Because we are unable to identify smelters and refiners that processed 3TG contained in the PoNS device and we do not have any direct supply relationships with the companies that supply to our contract manufacturer, our ability to respond to risks in our supply chain is limited.

Step 4: Carry out Independent Third-Party Audit of Supply Chain Due Diligence at Identified Points in the Supply Chain

Our manufacturer identified 233 unique smelters or refiners used that may have been used to process 3TG in the products it manufactures. For the reasons noted above, we expect that few of the 233 unique smelters or refiners identified by our manufacturer actually processed the 3TG in the PoNS device. If we contract to manufacture the PoNS device in the future, to the extent that smelters or refiners are identified to us and reasonably expected to be part of our supply chain, we plan to utilize and rely on information made available by the RMI concerning independent third-party audits of smelters and refiners to assess smelter and refiner due diligence and to determine whether the smelter or refiner is Responsible Minerals Assurance Process (RMAP) compliant.

Step 5: Report on Supply Chain Due Diligence

We filed this Form SD and Conflict Minerals Report with the SEC and made these documents available on our website at https://heliusmedical.com/index.php/investor-relations/sec-filings.

Due Diligence Results

Our sole manufacturer responded that smelters in its supply chain do source from Covered Countries and that the 3TG in products it manufacturers are not entirely from recycled or scrap sources. Our manufacturer identified 233 unique smelters or refiners that may have been used to process 3TG in the products it manufactures. Because our manufacturer's CMRT is company-wide and not specific to the Company or the PoNS device and given the large number of identified smelters and refiners, the relative size of our operations compared to our manufacturer and the limited number of PoNS devices we have contracted to manufacture to date, we expect that few of the 233 unique smelters or refiners identified by our manufacturer that may have been used to process 3TG in the products it manufactures actually processed the 3TG in the PoNS device. For this reason, we determined that we do not have sufficient information to reasonably identify the particular smelter or refiner that processed the 3TG in the PoNS device and thus did not list smelters or refiners in this Conflict Minerals Report. Further, we were unable to determine whether the 3TG contained in the PoNS device originated in the Covered Countries. Our sole manufacturer reported that it requires its direct suppliers to be DRC conflict-free (free of minerals that directly or indirectly finance or benefit armed groups in Covered Countries), but some of the smelters or refiners identified by our manufacturer were not RMAP compliant or participating in a certification program.

Steps to be Taken to Mitigate Risk

To date, we have contracted to manufacture a limited number of PoNS devices for engineering and design verification testing and for our FDA submission as well as commercial devices for launch inventory for commercialization in Canada. If we contact to manufacture the PoNS device in the future, at such time, we will consider the following improvements to mitigate risk of sourcing 3TG that benefit armed groups: establishing a cross functional conflict minerals team; creating a policy with respect to sourcing 3TG; and, to the extent that smelters or refiners are identified to us and reasonably expected to be part of our supply chain, to utilize information made available by the RMI concerning independent third-party audits of smelters and refiners to assess whether a reported smelter or refiner is RMAP compliant.