F8.2.1-4 Periodic Safety Update Report (PSUR)

Rev 1.0

Company Name & Address:	**SRN #:**	US-MF-000002014
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Device Family Name:	**Date prepared:**	2022-05-19
Oasis	**Year / Time Period for PSUR:**	2021-05-01 to 2022-05-01
Product Numbers:	**Device Classification:**	Class IIa
1.9.4.12	**Technical Document File No.:**	Doc#:455
	Basic UDI-DI No.:	00857198006006

PSUR Approved By (Name/Title):	**Signature:**	**Date:**
Thierry Breant, CEO, D&D, Production	Digitally signed by Thierry Breant	2022-05-23
David Mayton, Clinical Product Director, QMR/PRRC	Digitally signed by David Mayton	2022-05-23
Rebekah May, Clinical Product Manager	Digitally signed by Rebekah May	2022-05-23
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Wally Donlan, Customer & Product Manager	Digitally signed by Wally Donlan	2022-05-23
John Zurita, Sales Director	Digitally signed by John Zurita	2022-05-23

Date PSUR submitted to Notified Body:	2022-05-23	**Submitted via Eudamed (Class III or Implantable devices):**	☒ NA ☐ Yes Date:	

Segami has prepared this PSUR for Oasis for compliance with the Medical Devices Regulation (MDR) EU 2017/745 and in accordance with our QPR 8.2.1 Feedback and Post Market Surveillance.

This PSUR contains information from our PMS Plan activities for Oasis for the time period specified above.

1. Conclusions of the benefit-risk determination:

The overall risk for the entire system viewed from a broad perspective has been evaluated and support that the hazards associated with the device do not present an unreasonable risk to the user, patient, or environment. Segami Corporation has utilized FMEA, design inputs, design outputs, review of conflicting requirements, and review of the instruction for use to evaluate the risks associated with the device. Based on consideration and analysis of the software risk management team, a total of 23 risks were identified with the design and use of the software. As the software is not connected to the patient, nor provides or receives energy from the patient, and is only used as a supporting diagnostic tool for healthcare professionals, initially all risks were considered moderate risks prior to Segami taking mitigation risk reduction efforts. Following mitigation efforts, the residual risks indicated 20 low risks and 3 moderate risks. Risk Benefit analysis was performed on the three moderate identified residual risks. The residual risks have been determined to be acceptable as shown in the risk assessment and benefit-risk analysis.

2. Main findings of the PMCF *(per the PMFC Plan & Report)*:

As a result of the PMCF analysis completed April 2022

- No new hazards were identified
- No new identifiable side-effects or contraindications
- There is no evidence of misuse or off-label use of Oasis and the intended purpose was verified
- The safety and performance of Oasis was confirmed and the benefit-risk ratio was determined to be acceptable

3. Volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device:

Sales Data Table

	Year 2022 (as of 2022-04-28)	Year 2021	Year 2020	Year 2019
Sales Volume	22 licenses sold	66 licenses sold	48 licenses sold	54 licenses sold
Estimate of Population using Device	Approximately 2,220 users	Approximately 2,170 users	Approximately 2,040 users	Approximately 1,950 users
Usage Frequency (where practicable)	Approximately 135,864 uses per month	Approximately 132,804 uses per month	Approximately 124,848 uses per month	Approximately 119,340 uses per month

4. Rational and description of any preventive and corrective actions taken:

There were 4 CAPAs in the past 12 months:

1. CAPA ID#:60 – Customer reported higher SUV values than expected. After an investigation was conducted, this was verified and attributed to an unexpected decay correction method used on a PET scanner. This issue was fixed and the customer's workstations patched. It was determined no other Segami customers used this method of decay correction and all future Oasis versions will contain the corrected code.
2. CAPA ID#:61 – During an internal audit, a minor non-conformance was issued regarding the engineering change order form used within Segami's QMS. This form was improved by the addition of two radio-buttons added to the form:
   "*Is there an impact to the Quality Management System?"* and *"Is there an impact to the Product (Oasis)?",* along with an additional text box "Risk Comments" to provide explanations when a risk is identified.
3. CAPA ID#:62 – During an internal audit, a minor non-conformance was issued regarding Segami's regulatory reporting procedures not being current for Europe and Canada. Updated guidance was added to the forms and "Medical Problem Report" was changed to "Incident Reporting" (for Canada) and "MDVR – Medical Device Vigilance Report" was changed to "MDIR – Medical Device Incident Reporting" (for Europe). These forms were updated.
4. CAPA ID#:63 –During an internal audit, an OFI was issues regarding Segami's risk management procedure, which was still based on EN ISO 14971:2012 and not updated to reflect EN ISO 14971:2019. The forms and procedures were updated as required.

Health Canada Summary Report (CMDR section 61.4)

Canada Sales

Canada Sales by Province x 2 years:

Canada	May 2020 - April 2021	May 2021 - April 2022
Atlantic Provinces	0	0
Central Canada	3	0
Prairie Provinces	6	2
West Coast	0	0
Northern Territories	0	0
Total # of licenses sold	**9**	**2**

Risk Document Review

A. Adverse Effects: Though Oasis is intended to be used by trained medical professionals, the adverse effects related to the misuse of the device can lead to misdiagnosis and delays in treatment. These identified risks are mitigated as far as possible using risk controls within Segami's Risk Management program.

B. Complaint Handling: There were no Complaints in the current year, and There was one Type II complaint reported 2021-05-14. This is logged in Segami's QMS under Complaints – ID#:3, CAPA#:60. The proper procedure per QPR 8.2.3 Main Recall Procedure (Doc#:604) was followed. Doc#:575, HC Reportable Event

Decision and Doc#:574, Adverse Event Determination form were completed and no regulatory reporting was required.

C. Reportable Incidents per CMDR 59(1): There were no reportable incidents in the current or prior year.

D. Serious risks of injury per CMDR 61.2(2): Oasis does not come into contact with the patient, rather, it is used by healthcare professionals that are trained. All training sessions are documented by the Segami application specialist and the training evaluation forms are stored in QMS. The highest risk to the patient would be a misdiagnosis possibly leading to inappropriate treatment or a delay in treatment. These risks are mitigated by ensuring users are properly trained and having a user manual available to all users (an electronic version is included on all Oasis workstations). Oasis is a mature product and though this scenario has never occurred since the original Oasis release, Segami remains vigilant with respect to all associated risks to the device.

E. Analysis of Data in Summary Report: Evidence shows Oasis remains user-friendly, safe and effective. The overall risk for the entire system has been evaluated and support that the hazards associated with the device do not present an unreasonable risk to the user, patient, or environment. The residual risks and benefit-risk analysis have been determined to be acceptable.

F. Risk – Benefit Analysis:

1. Any benefits less than anticipated: No
2. Risks:
    a. Probability of event higher occurrence than anticipated? No
    b. If an event occurred, consequences of event could be more serious than anticipated? No
    c. Any New Risks identified? No
    d. Conclusions of Risk – Benefit Analysis: After analysis of the post-market proactive and reactive data, Oasis remains safe and effective. The overall risk for the entire system viewed from a broad perspective has been evaluated and support that the hazards associated with the device do not present an unreasonable risk to the user, patient, or environment. The residual risks and benefit-risk analysis have been determined to be acceptable. No regulatory reporting was required. Segami remains vigilant and we continue to gather data on a regular basis.

Note: Should analysis indicate that Risk – Benefit has changed to more severe, the Minister must be notified via Health Canada.