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

Rev 1.1

Company Name & Address:	**SRN #:**	US-MF-000002014
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Device Family Name:	**Date prepared:**	2024-04-03
Oasis	**Year / Time Period for PSUR:**	2022-05-01 to 2024-04-03
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:**
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David Mayton, Clinical Product Director, QMR/PRRC	Digitally signed by David Mayton	2024-04-03
Rebekah May, Clinical Product & Business Development Manager	Digitally signed by Rebekah May	2024-04-03
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Date PSUR submitted to Notified Body:	2024-04-04	**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 Segami's PMS planned activities for Oasis for the time period specified above.

1. Conclusions of the benefit-risk determination:

After analysis of the post-market proactive and reactive data, there are no unknown side-effects, contraindications, or emerging risks identified, and Oasis remains user-friendly, safe and effective while using well-established technology. 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.

There were no adverse event reports, incident reports, product recalls/FSCA, or advisory notices for the reporting time period. There were no product related corrective or preventive actions necessary. There has been no identified off-label misuse of the device.

2. Main findings of the PMS/PMCF:

PMS:

PMS was completed April 2024 and the following proactive and reactive data was analyzed:

- Summary of Oasis Complaints including Adverse Event Reporting and Recall / FSN / FSCA
- Trend Reporting
- New and Revised Regulatory Requirements and External Standards
- Publications Review
- Market Research, Literature, Articles and Journals Reviewed
- Post-Market Study: "Application Usage Statistics and Error Logs"
- Cybersecurity
- Summary of Production Results
- Summary of Servicing & Installation Activities
- Clinical Studies / Field Evaluations
- Customer Surveys / Market Surveys / Customer Suggestions
- Sales / Demo / Marketing / Tradeshow Feedback
- Summary of Product Non-Conformances (ITL)
- Country Database Searches – includes FDA MAUDE, FDA recalls, Health Canada recalls, Brazil recalls, and adverse events for each EU country that Oasis has been distributed.

- CAPA

After analyzing the PMS data, no new hazards were identified in the device. See Doc#:513, *PMS Analysis and Summary Rev1.9*

PMCF:

While there are no "unknowns" with the device, Segami conducts PMCF to proactively collect and evaluate clinical data with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence. As a result of the PMCF analysis completed March 2023

- 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

See Doc#:687, *PMCF Report Rev1.1*

3. Global Sales:

Global Sales Data Table

The data included uses a 5-year lookback period.

Legend:
EEA = European Economic Area
TR = Turkey
XI = Northern Ireland
N = Reporting Day + preceding 12 months (1 April 2023 - 1 April 2024)
N2 = 1 April 2022 - 1 April 2023
N3 = 1 April 2021 - 1 April 2022
N4 = 1 April 2020 - 1 April 2021
N5 = 1 April 2019 - 1 April 2020

Segami Oasis Client, Basic UDI-DI: 00857198006006																
Region	Total Number of Licenses	Reporting Day + preceding 12 months (N)	Type II Complaints (N)	Reportable Incidents (N)	N - 12 months (N2)	Type II Complaints (N2)	Reportable Incidents (N2)	N - 24 months (N3)	Type II Complaints (N3)	Reportable Incidents (N3)	N - 36 months (N4)	Type II Complaints (N4)	Reportable Incidents (N4)	N - 48 months (N5)	Type II Complaints (N5)	Reportable Incidents (N5)
EEA + TR + XI	**20**	1	0	0	0	0	0	3	0	0	11	0	0	5	0	0
United States	**110**	10	0	0	12	0	0	21	0	0	38	0	0	29	0	0
Canada	**8**	2	0	0	1	0	0	2	0	0	3	0	0	0	0	0
Latin America	**26**	6	0	0	2	0	0	9	0	0	4	0	0	5	0	0
Rest of World	**28**	1	0	0	10	0	0	6	0	0	2	0	0	9	0	0
Worldwide	**192**	**20**	**0**	**0**	**25**	**0**	**0**	**41**	**0**	**0**	**58**	**0**	**0**	**48**	**0**	**0**

Regarding the usage frequency of the device, an estimation can be made using the post-market study, *"Application Usage Statistics and Error Logs"*, where 6 hospitals were sampled to get each hospitals total number of Oasis usages per month, then averaged the 6 hospitals (4 Canadian, 2 U.S.) to obtain an average of 1105 Oasis usages per site per month. The number can vary based on the number of trained users at each site, total number of licenses purchased, and volume of nuclear medicine studies performed by the site.

Health Canada Summary Report (CMDR section 61.4)

Canada Sales

Canadian sales and distribution by Province:

Canada Only, Segami Oasis Client, Basic UDI-DI: 00857198006006																
Canada Region	Total Number of Licenses	Reporting Day + preceding 12 months (N)	Type II Complaints (N)	Reportable Incidents (N)	N - 12 months (N2)	Type II Complaints (N2)	Reportable Incidents (N2)	N - 24 months (N3)	Type II Complaints (N3)	Reportable Incidents (N3)	N - 36 months (N4)	Type II Complaints (N4)	Reportable Incidents (N4)	N - 48 months (N5)	Type II Complaints (N5)	Reportable Incidents (N5)
Atlantic Provinces	**0**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Central Canada	**1**	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Prarie Provinces	**10**	2	0	0	1	0	0	2	0	0	2	0	0	3	0	0
West Coast	**0**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Northern Territories	**0**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Canada Total	**11**	**2**	**0**	**0**	**1**	**0**	**0**	**2**	**1**	**0**	**2**	**0**	**0**	**3**	**0**	**0**

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 Type I or Type II complaints in the previous 24 month period.

C. Reportable Incidents per CMDR 59(1): There were no reportable incidents in the reporting period.

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 by a cross-functional team of experts with application knowledge /clinical expertise 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. Benefit – Risk 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 Benefit – Risk 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: In the event that benefit-risk has changed to more severe, the Minister shall be notified via Health Canada.