

## ENCLOSURE 3

### SHINE MEDICAL TECHNOLOGIES, INC.

#### SHINE MEDICAL TECHNOLOGIES, INC. PRELIMINARY SAFETY ANALYSIS REPORT REVISIONS RESULTING FROM REQUEST FOR ADDITIONAL INFORMATION RESPONSES

##### SUMMARY OF PRELIMINARY SAFETY ANALYSIS REPORT CHANGES PUBLIC VERSION

SHINE has determined that Preliminary Safety Analysis Report (PSAR) changes described in letters dated October 15, 2014; December 3, 2014, February 6, 2015; April 3, 2015; and May 1, 2015 can be incorporated. The following table provides a listing of the requests for additional information (RAIs) in which SHINE provided a response describing a change to the PSAR. In addition, the table provides reference to submittal information containing the applicable SHINE Response and the affected PSAR pages for each change.

A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 5.

RAI Number	SHINE Letter Number	Letter Date	Accession Number	Affected Preliminary Safety Analysis Report Page(s)
RAI 1.3-1	SMT-2014-033	October 15, 2014	ML14296A189	Figure 1.3-3
RAI 2.4-5	SMT-2014-040	December 3, 2014	ML14356A527	2.4-18 and 2.4-32
RAI 2.5-6	SMT-2014-040	December 3, 2014	ML14356A527	3-29
RAI 2.2-3	SMT-2015-004	February 6, 2015	ML15043A404	2-iv, 2.2-18, 2.2-18a, 2.2-18b, 2.2-18c, 2.2-18d, 2.2-18e, 2.2-18f, 2.2-24, 2.2-40a, 2.2-40b, 2.2-40c, 2.6-2, and 2.6-3
RAI 2.2-4	SMT-2015-004	February 6, 2015	ML15043A404	2-iii, 2.2-5, 2.2-6, 2.2-7, 2.2-8, 2.2-25, 2.2-28, 2.2-29, 2.2-30, 2.2-33, 2.2-34, 2.2-35, 2.6-2, and 2.6-3
RAI 3.2-1	SMT-2014-040	December 3, 2014	ML14356A527	2.3-12
RAI 3.5b-2	SMT-2015-012	April 10, 2015	ML15120A248	3-104 and 3-104a
RAI 4a2.6-2	SMT-2014-033	October 15, 2014	ML14296A189	4a2-38
RAI 4b-1	SMT-2014-033	October 15, 2014	ML14296A189	4b-9
RAI 4a2.8-2	SMT-2014-040	December 3, 2014	ML14356A527	4a2-26 and 4a2-27
RAI 6a2.2-5	SMT-2014-033	October 15, 2014	ML14296A189	6a2-6
RAI 6a2.2-6	SMT-2014-033	October 15, 2014	ML14296A189	6a2-7
RAI 6a2.2-10	SMT-2014-033	October 15, 2014	ML14296A189	1-10, 6-ii, 6a2-4, 6a2-5, 6a2-8a, and 6a2-9
RAI 6b.2-2	SMT-2014-033	October 15, 2014	ML14296A189	6b-5

<b>RAI Number</b>	<b>SHINE Letter Number</b>	<b>Letter Date</b>	<b>Accession Number</b>	<b>Affected Preliminary Safety Analysis Report Page(s)</b>
RAI 6b.2-3	SMT-2014-033	October 15, 2014	ML14296A189	6b-6
RAI 6b.2-5	SMT-2014-033	October 15, 2014	ML14296A189	1-10, 6-ii, 6b-3, 6b-4, 6b-9a, and 6b-10
RAI 6b.2-6	SMT-2014-040	December 3, 2014	ML14356A527	6b-2 and 6b-3
RAI 6b.3-24 <sup>(a)</sup>	SMT-2015-014	May 1, 2015	ML15131A464	6b-12
RAI 6b.3-27 <sup>(b)</sup>	SMT-2015-014	May 1, 2015	ML15131A464	6b-17 and 6b-18
RAI 11.1-5	SMT-2014-033	October 15, 2014	ML14296A189	11-20
RAI 11.2-3	SMT-2014-033	October 15, 2014	ML14296A189	11-54
RAI 11.2-4	SMT-2015-004	February 6, 2015	ML15043A404	9b-48, 9b-49, 9b-50, Figure 9b.7-5, and 11-50
RAI 12.1-1	SMT-2014-033	October 15, 2014	ML14296A189	11-6, 11-7, 11-8, 11-10, 11-11, 11-22, Figure 11.1-1, 11-58, 12-iii, 12-1, 12-3, 12-4, and Figure 12.1-1
RAI 12.1-2a	SMT-2014-033	October 15, 2014	ML14296A189	12-3
RAI 12.1-2b	SMT-2014-033	October 15, 2014	ML14296A189	12-3
RAI 12.2-1a	SMT-2014-033	October 15, 2014	ML14296A189	12-5
RAI 12.2-1b	SMT-2014-033	October 15, 2014	ML14296A189	12-5
RAI 12.2-2	SMT-2014-033	October 15, 2014	ML14296A189	12-6
RAI 12.2-3	SMT-2014-033	October 15, 2014	ML14296A189	12-6
RAI 12.3-1b	SMT-2014-033	October 15, 2014	ML14296A189	12-7 and 12-7a
RAI 12C.1-3b	SMT-2015-004	February 6, 2015	ML15043A404	12-13
RAI 13a2.1-2	SMT-2014-033	October 15, 2014	ML14296A189	4a2-59 and 4a2-60
RAI 13a2.1-8	SMT-2014-040	December 3, 2014	ML14356A527	13a2-3

- a) PSAR Revision originally described in the SHINE Response to RAI 6b.3-10 (SMT-2014-040), but modified based on the SHINE Response to RAI 6b.3-24.
- b) PSAR Revision originally described in the SHINE Response to RAI 6b.3-6 (SMT-2014-040), but modified based on the SHINE Response to RAI 6b.3-27.