Appendix 2

Medical Device Periodic Safety Report

I. Medical device product information

(I) License number or listing number:

(II) Product name in Chinese:

(III) Product name in English:

(IV) Model number:

(V) Name of Manufacturer:

(VI) Country of Manufacturer:

(VII) License holder or firm that has completed the listing:

(VIII) Indications: (Shall be provided for indications that require surveillance)

II. Period of safety surveillance (Start date of the Stage 1 surveillance shall not be later than the date of listing, license issuance, or announcement, and each stage shall be a period of half a year.)

Full surveillance period: _____(MM/DD/YYYY) – _____(MM/DD/YYYY)

Start and end date of Stage 1 data: _____(MM/DD/YYYY) ~_____(MM/DD/YYYY)	Deadline for submission: _____ (MM/DD/YYYY)
Start and end date of Stage 2 data: _____(MM/DD/YYYY) ~_____(MM/DD/YYYY)	Deadline for submission: _____ (MM/DD/YYYY)
Start and end date of Stage 3 data: _____(MM/DD/YYYY) ~_____(MM/DD/YYYY)	Deadline for submission: _____ (MM/DD/YYYY)
Start and end date of Stage 4 data: _____(MM/DD/YYYY) ~_____(MM/DD/YYYY)	Deadline for submission: _____ (MM/DD/YYYY)
Start and end date of Stage 5 data: _____(MM/DD/YYYY) ~_____(MM/DD/YYYY)	Deadline for submission: _____ (MM/DD/YYYY)
Start and end date of Stage 6 data: _____(MM/DD/YYYY) ~_____(MM/DD/YYYY)	Deadline for submission: _____ (MM/DD/YYYY)

* Extend the data field if necessary

III. Data organization (Additional explanation is required if the period of time of the data collected overseas for statistics is different from the start and end date of the local surveillance period.)

(I) Number of local and overseas users

Surveillance Period	Estimated number of users (or times)	
	Local	Overseas
Stage 1		
Stage 2		
Stage 3		
Stage 4		
Stage 5		

Stage 6		
Total number of users:		

* Extend the data field if necessary

(II) Total use by local medical institutions (Please specify if the device is rented.)

Level of medical institutions	Quantity sold	Estimated number of users (or times)
Total quantity		

* Extend the data field if necessary

(III) Local and overseas number of adverse events (Non-serious adverse events shall include customer complaints.)

Type	Serious adverse event(s)		Non-serious adverse event(s)	
	Local	Overseas	Local	Overseas
Stage 1				
Stage 2				
Stage 3				
Stage 4				
Stage 5				
Stage 6				
Total number of events				

* Extend the data field if necessary

IV. Collection of adverse event information (Please present the content of adverse events occurred during this stage using line listing.)

(I) Local medical device serious adverse event(s)

(II) Local medical device non-serious adverse event(s)

(III) Overseas medical device serious adverse event(s)
(Please specify if the event was reported to a foreign competent authority.)

(IV) Overseas medical device serious adverse event(s)

(V) Domestic and international academic journals, literature, and case reports published in academic conferences