“吉爾得”酷思塑平系統上市後安全監視計畫書
“Zeltiq”CoolSculpting System Periodic Safety Update Report (PSUR) Plan

A. 受監視產品資訊 (Monitor Product information):

- 產品中文名稱 (Product name in Chinese): “吉爾得”酷思塑平系統
- 產品英文名稱 (Product name in English): “Zeltiq” CoolSculpting System
- 產品型號/樣式(Product model / type): BRZ-AP2-020-000 / Coolmini applicator
- 許可證字號 (Registration license number in Taiwan): 衛部醫器輸字第 028216 號
- 製造廠名稱 (Name of manufacturing site): ZELTIQ AESTHETICS, INC.
- 製造廠地址 (Address of Manufacturing site):
  (O) 4410 Rosewood Dr Pleasanton, CA 94588, USA
  (P) 5996 Gleason Drive, Dublin, CA 94568, USA
- 許可證持有商名稱 (Name of pharmaceutical license holder)：台灣愛力根藥品股份有限公司
- 許可證持有商地址 (Address of pharmaceutical license holder): 臺北市中正區羅斯福路 2 段 102 號 9 樓

B. 監視計畫背景 (Background of PSUR):

為確保病患於接受“吉爾得”酷思塑平系統治療頦下區時的安全，本公司擬於收集治療該部位之治療程序及相關治療數據以進行安全監視。

To ensure patient safety while receiving “Zeltiq” CoolSculpting System treatment at submental area. We plan to collect all patient’s treatment process and respective treatment data while they are receiving treatment at before mentioned area for post-market surveillance.

C. 安全監視計畫目的 (Purpose of PSUR):

為符合衛生福利部食品藥物管理署“藥物安全監視管理辦法”第二條規定，建立「“吉爾得”酷思塑平系統」之上市後安全監視計畫及程序。監視計畫目的為下列項目(包括但不限於):

- 評估範圍：使用本產品時搭配 CoolMini 握持器(型號 BRZ-AP2-020-000) 治療頦下區的安全相關資料。
- 嚴重藥物不良反應：依據衛生福利部食品藥物管理署「嚴重藥物不良反應通報辦法」內容。

To comply with Taiwan Food and Drug Administration Regulations for Drug Safety Monitoring Article 2 to initiate “Zeltiq” CoolSculpting System Post-market surveillance report protocol and it procedure. Monitor purpose as below (include but not limit with):

Monitor Scope: Safety related data while using system’s applied applicator: CoolMini (Model number: BRZ-AP2-020-000) provide treatment at submental area.

Serious Adverse Reaction: Severe Adverse Reactions of Medicaments which regulated by Taiwan Food and Drug Administration.

D. 監視或研究對象 (Monitor or Research subject):

病患接受治療頦下區以改善脂肪凸出的外觀。

Treatment of patients with submental area to assist in improving the appearance of protruding fat.

E. 評估指標與計畫之關聯性 (Relation between Evaluation target and Protocol):

本計畫是為追蹤及監視治療頦下區時產品安全性，以增進該治療部位的治療體驗及產品安全性。

This PSUR is to follow and monitor product safety for treatment at submental area to ensure and improve respective area treatment experience and product safety.

F. 資料評估、記錄暨分析方法以及監控提供時間點（Data evaluation, Record and analysis method and PSUR providing timeframe):

事件通知表(附件 1)將用於收集以及記錄於監視期間發生的所有嚴重藥物不良反應。相關表格適用於收到病患的訊息回饋或是經由醫師診斷時進行填寫。資料將基於事件嚴重度、預期度以及處理結果進行評估。

自本產品取得治療頦下區治療核准日或是依衛生福利部食品藥物理署指示起為期三年。醫療器材定期安全性報告需每個六個月提供乙次並於數據鎖住後一個月內提交。於繳交第六次醫療器材定期安全性報告後二個月應提交三年監視期滿醫療器材之安全性總結報告。

The event report form (attachment 1) will use for collecting and recording all serious adverse event that receive in PSUR monitor period. Respective form can be fill while receive patient response or through physician diagnostic. Data will be evaluate based on event seriousness, expectedness and resolved result. PSUR monitor period will be 3 years from the date of submental area indication has approve from TFDA or based on instruction from TFDA.

Regular PSUR shall be provide in 6 months base and submission due shall be within 1 month after DLP (Data Lock Point) a 3 Years PSUR summary shall be provide within 2 months after 6th regular PSUR submission.

嚴重藥物不良反應案例應依最新管理辦法進行通報。醫療機構及藥局應於得知涉及病人死亡或危及生命之嚴重醫療器材不良反應之日起 7 日內向衛生福利部食品藥物管理署或是其委託單位進行通報，或是於得知事件起 48 小時內通知許可證持有商。許可證持有商，應於得知嚴重醫療器材不良反應之日起 15 日內通報。

嚴重醫療器材不良反應係指因使用醫療器材致生下列各款情形之一者：

1. 死亡。
2. 危及生命。
3. 造成永久性殘疾。
4. 胎嬰兒先天性畸形。
5. 導致病人住院或延長病人住院時間。
6. 其他可能導致永久性傷害需做處置者。

For event that falls under Severe Adverse Reactions, reporting procedure shall follow with most recent Regulations for Reporting Severe Adverse Reactions of Medicaments.

The **medical care institution** and pharmacy can undertake reporting within **7 days** from the day of becoming aware to the central competent health authority (TFDA) or its commissioned institution (ADR center) or **contact pharmaceutical license holder sales representative** within **48hrs** from becoming aware.

The **pharmaceutical license holder** shall undertake reporting within **15 days** from the day of becoming aware.

The term "severe adverse reaction of medicament" as used in before mentioned Regulations shall refer to the use of a medicament resulting in occurrence of one of the conditions listed in the following subparagraphs:

1. Death;
2. Life-threatening condition;
3. Permanent disability;
4. Congenital anomaly/birth defect of fetus/infant;
5. Inpatient hospitalization or prolongation of existing hospitalization;
6. Others that may result in permanent injuries requiring intervention.

G. 資料收集以及格式 (Data collection and format)

1. 事件通報表(Event report form)
2. 定期安全性報告格式(Regular PSUR format)
3. 三年監視期滿醫療器材之安全性總結報告(3 Years PSUR Summary format)

附件一 **Attachment 1**

“吉爾得”酷思塑平系統事件通報表

“Zeltiq” CoolSculpting System Event report form

A. Monitor Product information: 受監視產品資訊		
Product name in Chinese	產品中文名稱:	“吉爾得”酷思塑平系統
Product name in English	產品英文名稱:	“Zeltiq” CoolSculpting System
Registration license number in Taiwan	許可證字號	衛部醫器輸字第 028216 號
Product model / type	型號 / 樣式:	Coolmini
Serial Number (SN)	序號:	
Treatment indication area	治療部位:	Submental area (頦下區)

B. Patient Background information 病患背景資訊

Patient code 病患代碼		Gender 性別: ☐ Male 男 ☐ Female 女	Age 年齡:

Height 身高: _____(cm 公分)	Weight (Before treatment) 治療前體重: _____(kg 公斤)	Race 人種: ☐ Asian 亞洲 ☐ Caucasian 高加索 ☐ African American 非裔美國人 ☐ Multi 2+ 混血 _____ ☐ Others 其他 _____
Fitzpatrick Skin Type 菲茲派崔克膚色分類 ☐ I ☐ II ☐ III ☐ IV ☐V ☐VI	Weight (After treatment) 治療後體重: _____(kg 公斤)	

Pertinent Medical History (i.e. Hernia, Chemotherapy, Implants, Chronic Pain):
相關病史（即疝氣，化學療法，植入物，慢性疼痛）

Previous Surgeries / Dates of Procedures/ Surgeries / Recent Delivery:
既往手術/手術日期/手術/最近生產

Pertinent Medications: (i.e. Anticoagulant, Insulin, Immunosuppressant, Accutane, etc.):
相關藥物：（即抗凝劑，胰島素，免疫抑製劑，A 酸等）

Treatment summary (related to the current symptom) 治療概要 (與近期症狀相關):

Remark 備註:
Manual message occur immediately post treatment 治療後立即徒手按摩:
☐Y 是 ☐N 否 ; If Yes, how long 如果有請說明按摩時間: _____ minutes(分鐘)

Multi-Sculpting (If was treated with 2 or more applicator at same time, please describe placement)
其他併用雕塑 (如同時接受 2 種或 2 種以上握持器治療, 請敘明部位):

C. Hospital / Clinic information 醫療院所資訊	
Name of Hospital / Clinic 醫療院所名稱:	Contact information 聯絡資訊:
Name of provider who made diagnosis 診斷人員姓名: ☐ MD ☐ NP ☐ PA ☐ _____	Date of diagnosis (YYYY-MM-DD) 診斷日期:
Please describe the tissue characteristics for the treated area compared to non-treated areas: 與未治療部位相比，請說明被治療部位之組織特性:	
Is there a visibly enlarged tissue volume over the treated area? 被治療部位是否有可見的組織膨大情形?	
Is surgery required? ☐ Y 是 ☐ N 否 ☐ Undetermined 未判定 Kindly specify if undetermined (如未判定請詳述):	
If a Hernia: Was there a pre-existing hernia? 如有疝氣: 是否原本既有疝氣? ☐ Y 是 ☐ N 否 ☐ Unknown 未知 ☐ Other 其他: _____	
Does the diagnosis provider feel the hernia was the result of CoolSculpting? 診斷人員是否認為 CoolSculpting 為造成疝氣的原因?	
Please provide upcoming care coordination activities: (i.e., Follow-up calls, Clinic appointment, MD/Specialist appoints) 請提供未來相應的照護措施: (即追蹤訪問電話、門診預約、醫師/專員指派)	
Other Remark (其他備註):	

D. Severe Adverse Reaction 嚴重藥物不良反應 (D1-1)			
Inform pharmaceutical license holder 是否已通知許可證持有藥商: ☐ N 否 ☐ Y 是 _____ (Date and Time 通知日期與時間)			
Severe Adverse Reaction (Tick if have) **嚴重藥物不良反應 (請勾選)**		**Stage and Description** 階段與說明	**Date of awareness (YYYY-MM-DD)** 知悉日期 (年-月-日)
	Death 死亡	☐ During a Treatment: 治療時 ☐ Immediately after a treatment: 當下治療完畢時 ☐ After one to two weeks treatment: 治療一至兩週後 (Kindly Specify 請詳述 :)	
	Life-threatening condition 危及生命	☐ During a Treatment: 治療時 ☐ Immediately after a treatment: 當下治療完畢時 ☐ After one to two weeks treatment: 治療一至兩週後 (Kindly Specify 請詳述 :)	
	Permanent disability 造成永久性殘疾	☐ During a Treatment: 治療時 ☐ Immediately after a treatment: 當下治療完畢時 ☐ After one to two weeks treatment: 治療一至兩週後 (Kindly Specify 請詳述 :)	
	Congenital anomaly/birth defect of fetus/infant 胎嬰兒先天性畸形	☐ During a Treatment: 治療時 ☐ Immediately after a treatment: 當下治療完畢時 ☐ After one to two weeks treatment: 治療一至兩週後 (Kindly Specify 請詳述 :)	
	Inpatient hospitalization or prolongation of existing hospitalization 導致病人住院或延長病人住院時間	☐ During a Treatment: 治療時 ☐ Immediately after a treatment: 當下治療完畢時 ☐ After one to two weeks treatment: 治療一至兩週後 (Kindly Specify 請詳述 :)	
	Others that may result in permanent injuries requiring intervention 其他可能導致永久性傷害需做處置者	☐ During a Treatment: 治療時 ☐ Immediately after a treatment: 當下治療完畢時 ☐ After one to two weeks treatment: 治療一至兩週後 (Kindly Specify 請詳述 :)	

附件二 Attachment 2

“吉爾得” 酷思塑平系統 上市後定期安全性報告
“Zeltiq” CoolSculpting System Regular PSUR Report

A. 產品資料 Product information:

- ■ 產品中文名稱 (Product name in Chinese): “吉爾得” 酷思塑平系統
- ■ 產品英文名稱 (Product name in English): “Zeltiq” CoolSculpting System
- ■ 產品型號/樣式(Product model / type): BRZ-AP2-020-000 / Coolmini applicator
- ■ 許可證字號 (Registration license number in Taiwan): 衛部醫器輸字第 028216 號
- ■ 適應症 (Intended Use) : 本裝置之冷卻功能在搭配 CoolMini Applicator 治療頦下(submental)區的冷卻輔助改善脂肪凸出的外觀。
- ■ 製造廠名稱 (Name of manufacturing site): ZELTIQ AESTHETICS, INC.
- ■ 製造廠地址 (Address of Manufacturing site):
  (O) 4410 Rosewood Dr Pleasanton, CA 94588, USA
  (P) 5996 Gleason Drive, Dublin, CA 94568, USA
- ■ 許可證持有商名稱 (Name of pharmaceutical license holder)：台灣愛力根藥品股份有限公司
- ■ 許可證持有商地址 (Address of pharmaceutical license holder): 臺北市中正區羅斯福路 2 段 102 號 9 樓

B. 安全性資料涵蓋期間 (PSUR monitor period)

- ■ 全程監視期間 (Target monitor period)
- ■ 本次報告監視期間(Monitor period in this report)
  本次送件為本產品於監視期第 □1st □2nd □3rd □4th □5th □6th 次送件 (Submission of PSUR)

C. 不良反應資料收集 (Adverse Event collection)

- ■ 國內嚴重醫療器材不良反應案件 (Domestic SAE (Line Listing)
- ■ 國內非嚴重醫療器材不良反應案件(Domestic non SAE related Adverse Event (Line Listing)
- ■ 國外嚴重醫療器材不良反應案件 (ROW (Rest of World) SAE (Line Listing)
- ■ 國內非嚴重醫療器材不良反應案件 (ROW non SAE related Adverse Event (Line Listing)
- ■ 收集國內外學術期刊文獻及學術研討會上發表之病例報告 (Regional and WW published paper and medical case (Line Listing)

D. 不良反應匯整表(Adverse Event matrix table)

事件類別 Event type	事件數 (Number of events)	
	國內 (Domestic)	國外 (ROW)
嚴重醫療器材不良反應案件 (SAE)		
非嚴重醫療器材不良反應案件 (Non SAE related Adverse Event)		
總計(嚴重+非嚴重醫療器材不良反應案件) Total (SAE + Non SAE related Adverse Event)		

E. 國內使用量 (Domestic usage calculation):

- ■ 本次報告監視期間國內使用數(使用人數) Domestic usage number (User number) in report mentioned monitor period
- ■ 截至本次數據鎖住之總使用量(使用人數) (Total usage number until this report DLP (User number)
- ■ 醫療機構使用情形 (Medical institute usage status in Taiwan)

醫療機構名稱 (Name of medical institute)	銷售數 (Sales number)	使用人數 (User number)

附件三 Attachment 3

“吉爾得” 酷思塑平系統 三年監視期滿醫療器材之安全性總結報告

“Zeltiq” CoolSculpting System 3 years PSUR summary

A. Product information

1. Product name in both Chinese Traditional and English and Registered number
   - ■ 產品中文名稱 (Product name in Chinese)： “吉爾得” 酷思塑平系統
   - ■ 產品英文名稱 (Product name in English)： “Zeltiq” CoolSculpting System
   - ■ 許可證字號 (Registered number) : 衛部醫器輸字第 028216 號
2. 產品型號/樣式(Product model / type): BRZ-AP2-020-000 / Coolmini applicator
3. 許可證字號 (Registration license number in Taiwan): 衛部醫器輸字第 028216 號
4. 適應症 (Intended Use)：本裝置之冷卻功能在搭配 CoolMini Applicator 治療頦下(submental)區的冷卻輔助改善脂肪凸出的外觀。
5. 製造廠名稱 (Name of manufacturing site): ZELTIQ AESTHETICS, INC.
6. 製造廠地址 (Address of Manufacturing site):
   (O) 4410 Rosewood Dr Pleasanton, CA 94588, USA
   (P) 5996 Gleason Drive, Dublin, CA 94568, USA
7. 製造廠所在國家 (Manufacturing site Country of Origin): USA
8. 許可證持有商(License holder in Taiwan): 台灣愛力根藥品股份有限公司
9. 國內外醫療器材銷售數量(Total distribution number in both ROW and Taiwan)

產品 (Product)	國內 (Domestic)	國外 (ROW)
“Zeltiq” CoolSculpting System – Coolmini applicator		

B. 全程監視期間 (Safety monitoring period): _(YYYY-MM-DD) ~ (YYYY-MM-DD)__

C. 衛生福利部（或前行政院衛生署）公告規定應監視項目之執行情形摘要(包括但不限於監視期間於國內出現之嚴重及非嚴重不良反應事件、不良品、客訴案件等特殊情況之統計及分析摘要，並檢討相關原因) (Summary of medical safety monitoring (Include but not limit to SAE (Serious Adverse Event), Non-SAE, defective medical devices, customer complaints and other individual case's statistics, analysis summary and root cause)

D. 世界各國醫療器材上市狀況(包括但不限於銷售至哪些國家及銷售數量分布、國外嚴重及非嚴重不良反應事件之統計及分析摘要等) (Worldwide marketing status (Include but not limit to distributed country and it sales volume, SAE and AE statistics and analysis summary)

E. 國內外衛生主管機關或藥商對於醫療器材安全性之採取行動(包括但不限於醫療器材下市或終止、許可證未如期更新、醫療器材銷售之限制、臨床試驗基於安全性考量之終止、使用方式修改、適應症或適用族群的變更、零組件之更改、仿單警語或注意事項之變更、安全性通告或回收訊息之發布等) (Action that has taken by Health authority or Manufacturer due to product safety (Include but not limit to termination of the product, renewal of the license is not scheduled, product sales restriction, termination of clinical study due to safety consideration, modification of the usage, indication or applicable ethnic group, changes in cautions,

safety notices or recall notices release …etc.)

F. 各國安全資訊方面的變更(包括但不限於醫療器材安全性相關之仿單資訊變更、醫療器材發生不良事件或已知副作用之頻率或嚴重程度有顯著增加趨勢之相關資訊等) (Update of Safety information changes in any country (Include but not limit to product safety related information, adverse event due to product itself, known side effect occurred rate or severity with significant increase …etc.)

G. 臨床試驗(包括醫療器材上市後與安全性相關之臨床研究或分析結果及安全性臨床研究之文獻發表；如查無相關文獻，請提供文獻查詢日期、所查詢之文獻資料庫及查詢條件) (Clinical study (include post-market and safety related study and/or analysis, safety related study's research publishing. If no related study research, kindly provide date of reference data survey, searched data base and searching criteria)

H. 利益-風險分析與風險管理計畫(包括事先未確認的危害、超過可接受風險的危害、風險重新評定及醫療受益與整體殘留風險分析)(Benefit – Risk analysis and Risk management plan (Include Unknown hazard, Exceed acceptable risk, Risk re-evaluation and Residual risk of medical benefit)

I. 總體安全性評估 (Overall Safety Evaluation)

J. 總結 (Conclusion)

附表一、醫療器材監視期滿總結報告摘要表

(Attach table 1 Table summary of medical device safety monitoring)

產品	**"吉爾得" 酷思塑平系統 – 搭配使用 Coolmini applicator**									
監視期間	國內推估使用總人數	國外推估使用總人數	國內嚴重不良反應事件數	國內非嚴重不良反應事件數	國外嚴重不良反應事件數	國外非嚴重不良反應事件數	國內期刊篇數	國外期刊篇數	國內病例發表篇數	國外病例發表篇數
相關附件索引編號										

Product	**"Zeltiq" CoolSculpting System – Coolmini applicator**									
Monitor Period	Estimate user in Taiwan	Estimate user in ROW	SAE number in Taiwan	Non-SAE number in Taiwan	SAE in ROW	Non-SAE number in ROW	Published paper number in TW	Published paper number in ROW	Published medical case in TW	Published medical case in ROW
(YYYY-MM-DD ~ YYYY – MM-DD)										
Reference number for respective information										

附表二、國內執行機構使用情形 (Attach table 2 Medical institute usage status in Taiwan)

“吉爾得” 酷思塑平系統 – 搭配使用 Coolmini applicator		
醫療機構名稱	銷售數	使用人數

“Zeltiq” CoolSculpting System – Coolmini applicator		
Name of medical institute	Sales number	User number