**Request Form for Special Request and Custom Devices**

**(To be used to document requests from the US market for Special Request or Custom devices. - may be completed by UOC USA)**

**Request Form Number: \_\_\_\_\_\_\_\_\_\_\_\_**

**Part 1 COMPLETED BY SALES MANAGER**

Sales Manager Name: Date of Request:

Requesting Surgeons First and Last Name:

Responsible Agent First and Last Name:

Will Agent cost share in the expense Provide details or rationale:

**Complete section 1 or 2 below. One form per request type.**

1. Is this a request to modify an existing instrument or implant?
2. Is the customization for an instrument or implant?
3. If so, what is the current part number?
4. Current Lot if a modification?
5. Current revision if modification?
6. What is the product name description?
7. What is the description of the change being requested?
8. Is this a request for a New Custom Instrument or Device not currently provided by United?
9. Product Name or Description?
10. What is the customization requested?

*Notice, UOC will request a prescription with credentials from the Surgeon for implant requests.*

You may include a picture or drawing of the nature of the request here.

**Part 2 UOC USA INTERNAL APPROVALS:**

Cost for Customization:

Agent cost share amount:

Agent consent for cost share obtained (required prior to approval)

**APPROVALS**

|  |  |  |
| --- | --- | --- |
| **Title** | **Signature** | **Date** |
| VP MARKETING |  |  |
| VP SALES |  |  |
| DIR. OPERATIONS |  |  |
| BRANCH MANGER |  |  |

**Part 3 UOC Taiwan:**

|  |  |
| --- | --- |
| **Special Request** |  |
| For Modification, is there any new risk introduced? |  |
| Is the modification approved? |  |
| Rationale for approval or denial |  |

|  |  |
| --- | --- |
| **Custom Device** |  |
| Will this request for a custom device be fulfilled? |  |
| Rationale for approval or denial |  |

Product Management Signature: Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Quality Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Part 4 UOC USA:**

|  |  |
| --- | --- |
| For modification, have all requirements been met? (no new risk, Taiwan approval, etc.) |  |
| For Custom devices, have all requirements been met? (prescription, Taiwan approval, etc.) |  |

Management Signature: Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Quality Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_