Requirements for Application for Compassionate Special Permit (CSP) for Registrable Medical Devices.

1. Letter of intent which will include a brief description of the patient, attending physician, list of specialists who will perform the administration of the medical device, quantity of the medical device required to perform the treatment and the proposed schedule of the medical attention.
2. Attending physician's profile.
3. License to Operate as Medical Device Importer/Distributor if the product is to be supplies by a company.
4. Letter of information regarding the importer if the medical device is to be imported by a private individual.
5. Certificate of Product Registration from the country of origin of the medical device to be used. If the medical device is locally manufactured, copy of the License to Operate as Medical Device Manufacturer.
6. Technical description of the medical device from the manufacturer; not downloaded from the company's website.
7. Justification letter from the attending physician regarding the urgency of the use of the medical device.
8. Medical abstract of the patient.
9. A waiver of FDA responsibility from any damage or injury arising from the use of the unregistered medical device to be signed by the applicant company, relative of the patient and the attending physician.
10. A commitment letter from the applicant that a medical report shall be submitted after the operation or use of the medical device in the patient.