

[Attached Form No. 1]

Application for Designation of an Orphan Device		Settlement period
		55 days
Applicant	Name of Manufacturer or importer	
	Name of representative	
	Location	(Tel :)
Product name (classification code and model No.)		
Relevant disease		
Producer		
<p>I would like to apply for designation of an Orphan Medical Device as mentioned in the above under Article 3 of the 「Rule on Designation of Orphan Medical Devices」 .</p> <p style="text-align: right;">Date:</p> <p style="text-align: center;">Applicant (sign or seal)</p> <p>To the Commissioner of Korea Food and Drug Administration</p>		
<p>※Required documents</p> <ol style="list-style-type: none">1. Data proving that the Medical Device falls under Orphan Medical Devices(Article 2)2. Data about the purpose of use, shape & structure, raw material, performance, instructions for use, and the principle of operation and specification of the product(Item 2 of Article 3)3. A written recommendation for designation of an Orphan Medical Device(Item 3 of Article 3)4. Alternative data to a written recommendation for designation of an Orphan Medical Device (provisory clause of Article 3)		

210mm×297mm(general paper 60g/m²(recyclable))

[별지 제2호서식]

희소의료기기 지정추천서

체 품 명
(분 류 번 호 및 형 명)

대 상 질 환

체 조 또는 수입업체명

대 표 자

소 재 지

체 조 원

위 의료기기가 「희소의료기기 지정에 관한 규정」 제3조에 따라 희소의료기기로 지정할 필요가 있다고 판단되기에 이를 추천합니다.

년 월 일

추천인

(서명 또는 인)

식품의약품안전청장 귀하

- 붙임 : 1. 추천경위 및 사유
2. 대체치료법 또는 대체의료기기 등에 대한 의학적 견해 및 그 근거
3. 대상질환에 대한 통계자료(인구대비 발생비율 등) 및 그 근거
4. 기타 참고의견

210mm×297mm(일반용지 60g/m²(재활용품))

[Attached Form No. 2]

A Written Recommendation for Designation of an Orphan Medical Device	
Product name (Classification code and model No.)	
Relevant disease	
Name of manufacturer and importer	
Name of representative	
Location	
Producer	
<p>It is deemed that the above-mentioned Medical Device is required to be designated as an Orphan Medical Device under Article 3 of the 「Rule on Designation of Orphan Medical Devices」 thus I would like to recommend such designation.</p> <p style="text-align: right;">Date:</p> <p style="text-align: right;">Recommender (sign or seal)</p> <p>To the Commissioner of Korea Food and Drug Administration</p>	
<p>Attachments : 1. Details and reasons for recommendation 2. Medical opinion and the grounds for alternative therapy or medical devices etc. 3. Statistical data(incidence rate of the population etc.) and the grounds for the disease 4. Other opinion for reference</p>	

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