

Application Information / Information de soumission						
*Licence Name/Nom de l'homologation:	Application Number/Numéro de soumission					
ТАДРАТН	312749					
Licence # / # de l'homologation:	Application Type/Type de soumission:					
0						
Manufacturer/Fabricant:	Company ID/Identificateur d'entreprise:					
THERMO FISHER SCIENTIFIC	151653					
Risk Class:	Rationale:					
3						
*Licence Type/Type d'homologation:	Rationale:					
Single Device 👻						
Contains Controlled Substance(s) Contains Drug(s) Contains Biological Material(s)						
*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications						

This Application is an Amendment to the IO in which the manufacturer is providing bridging studies for the original authorization.

	Screening Decision	
Accept		•
Emily Smalling		<b>Date</b> : Mar. 25, 2020
Device Licensing Services Division Medical Devices Bureau		



Check GMDN

GMDN Name	GMDN	GMDN Description	Issue	Action for Screener	Regulatory Action	Reference
	Code					Material