EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Origio

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification [1] issued on	Summary
IA/0019	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	25/08/2023	To update the legal manufacturer to CooperSurgical, Inc. and to reconfirm the Scientific Opinion granted under MDD (93/42/EEC) for the purpose of certification under MDR (MDR/2017/745). To update references of medical devices with HSA media and to remove a manufacturing site.
IA/0018	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	21/02/2023	To submit a 2nd step notification procedure.
IA/0017	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	08/09/2022	To submit a 2nd step notification procedure.

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

IB/0016	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	21/07/2021	To add a new manufacturing site for IVF media.
IA/0015	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	18/03/2021	To change the Notified Body from Presafe, Denmark A/S (Tuborg Parkvej 8, 2900 Hellerup, Denmark) to BSI Group The Netherlands B.V. (Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands).
IB/0014	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	13/07/2020	To introduce the new medium ORIGIO Handling (8310, 8311).
IB/0013	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	21/07/2017	To introduce new media: ORIGIO Gradient 90 (8401), 40/80 (8402), 40 (8403) and 80 (8404).
II/0012	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	04/08/2016	To replace the current source of albumin for Human Albumin Solution 20% manufactured by Instituto Grifols, Poligono Levante, C/Can Guasch 2, 08150 Parets del Valles, Barcelona, Spain.
IB/0011	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	15/06/2016	To add a new medium, Origio Sperm Wash (8405).
IB/0010	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	24/08/2015	To add a new medium, BlastGen (1205).
IB/0009	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	27/06/2014	To add a new medium, EmbryoGen (1204).
IB/0008	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	24/04/2014	To add a new medium, SAGE 1-Step (6701).
IB/0007	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	18/12/2013	To submit a 2nd step notification procedure.

IB/0006	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	29/11/2013	To add three new media, ORIGIO Sequential Fert (8301, 8302), ORIGIO Sequential Cleav (8303, 8304) and ORIGIO Sequential Blast (8305, 8306).
IB/0005	B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation	03/08/2011	To add a new medium, EmbryoGgen.
IB/0004	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	14/10/2010	To add two new media, MediCult Vitrification Cooling and MediCult Vitrification Warming.
IA/0003	B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients	15/04/2010	Changes in composition of two media: EmbryoAssist and BlastAssist.
IB/0002	IB_18_Replacement of an excipient with a comparable excipient	24/03/2010	To add a new medium ICSI Cumulase.
IA/0001	IA_08_b_02_Change in BR/QC testing - repl./add. manuf. responsible for BR - incl. BC/testing	18/01/2010	Change in the name of the applicant for the device approval and manufacturer from MediCult a/s to ORIGIO a/s, change in the manufacturer responsible for batch release for the finished product and change in the name of the Plasma Master File (PMF) Certificate Holder/ PMF Applicant.