510(k) Premarket Notification

Device Classification Name	Lenses, Soft Contact, Daily Wear
510(k) Number	K143431
Divice Name	Giselle (Polymacon) Daily Wear Soft (Hydrophilic) Contact Lenses (Clear And Tinted)
Applicant	I-Codi Co.,Ltd #959-9, Daechon-Dong Buk-Gu, KR
Applicant Contact	Yoo Hwan Park
Correspondent	EyeReg Consulting, Inc 474 Ne 61 st P1 Hillsboro, OR 97124
Correspodent Contact	Bret Andre
Regulation Number	886.5925
Classification Product Code	LPL
Subsequent Product Code	MVN
Date Received	12/01/2014
Decision Date	02/20/2015
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Ophthalmic
510k Review Panel	Ophthalmic
Type	Traditional
Summary	Summary
Reviewed By Third Party	No
Combination Product	No