510(k) Premarket Notification

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Device Classification Name	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
510(K) Number	K112542
Device Name	YOMURA SAFETY I.V. CATHETER
Applicant	YOMURA TECHNOLOGIES INC. NO. 2-3, KUNG 8TH ROAD SECOND INDUSTRIAL PARK New Taipei City, TW 244
Applicant Contact	Sherry Lin
Correspondent	YOMURA TECHNOLOGIES INC. NO. 2-3, KUNG 8TH ROAD SECOND INDUSTRIAL PARK New Taipei City, TW 244
Correspondent Contact	Sherry Lin
Regulation Number	880.5200
Classification Product Code	FOZ
Date Received	09/01/2011
Decision Date	02/08/2012
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No