

510(k) Premarket Notification

Device Classification Name	powered light based non-laser surgical instrument with thermal effect
510(K) Number	K111350
Model	EVOLUX V4110, EVOLIGHT V4110, EVOSTAR V4110, EVOLASE V4110
Device Name	MEDICAM EVOLUX, EVOSTAR, EVOLIGHT AND EVOLASE PULSED LIGHT SYSTEM
Applicant	MEDICAM INC. 7900 jean-brillon montreal, quebec,
Contact	philippe amar
Regulation Number	878.4810
Classification Product Code	ONE
Date Received	05/13/2011
Decision Date	09/29/2011
Decision	substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
summary	summary
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No
Combination Product	No