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Device Classification Name	Implant, Endosseous, Root-Form
510(K) Number	K140202
Device Name	TRAUSIM DENTAL IMPLANT SYSTEM
Original Applicant	JIANGSU TRAUSIM MEDICAL INSTRUMENT West Renmin Rd., Niutang Town, Wujin Dist. Changzhou City, Jaingsu Provicne, CN 213163
Original Contact	Luo Zhicong
Regulation Number	872.3640
Classification Product Code	DZE
Subsequent Product Code	NHA
Date Received	01/27/2014
Decision Date	12/12/2014
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Type	Traditional
Reviewed By Third Party	No
Combination Product	No