FDA Declaration Device Registration

Establishment Registration Number : 3010889828

Owner Operator Number : 10046523

DUNS Number : 865773902

Classification : Class I (General Controls)

Submission Type : 510(K) Exempt

Official Correspondent Address : BIOCYTECH CORPORATION SDN BHD (854649-T)
: 820, Simpang Empat, Jalan Lahat, Menglembu, 31450 Ipoh Perak Perak, MALAYSIA

United States Agent Representative : FDA Listing Inc.

Establishment Registration & Device Listing

Listing Number	Premarket Submission Number	Product Codes	Device Name	Activities
D215778	Exempt	LEA	PRESERVATIVE, CYTOLOGICAL – PATHTEZT PRESERVE CELL SOLUTION, NON GYN PRESERVE CELL SOLUTION, URINECELL PRESERVE CELL SOLUTION, EASYVIAL PRESERVE CELL SOULUTION, DENSITY REAGENT	Manufacturer
D215779	Exempt	KET	FILTERS, CELL COLLECTION, TISSUE PROCESSING PATHTEZT – GYN FILTER; NON GYN FILTER; URINECELL FILTER; DUAL FILTER; PRE-FILTER	Manufacturer
D215780	Exempt	KEW	SLIDES, MICROSCOPE – PATHTEZT CYTO-SLIDE; URINECELL SLIDE; IMAGER SLIDE; IHC SLIDE; PRECOAT SLIDE	Manufacturer
D215781	Exempt	LDW	FIXATIVE, ACID CONTAINING – PATHTEZT CYTOLYSIS SOLUTION	Manufacturer
D371008	Exempt	IEO	PROCESSOR, TISSUE, AUTOMATED – PATHTEZT PROCESSOR; PATHTEZT INFINITY WITH AUTOLOADER; PATHTEZT 2000; PATHTEZT EASYVIAL SLIDE PROCESSOR	Manufacturer

Date of Initial Registration: 2014-04-01

(FDA) Certificates(s) : Not Applicable – Self Declare Medical Device

BIOCYTECH CORPORATION SDN BHD 854649-T

Name: Michelle Ng
Position: Operation Director
BIOCYTECH CORPORATION SDN.BHD.