Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name _____

Subject: 510(k) Number _____

To: The Record

Please list CTS decision code _____
Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
Hold (Additional Information or Telephone Hold).
Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please Abbreviated Standards Data Form			
Is this a combination product? (Please specify category _____,			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

_____

(*If unclassified, see 510(k) Staff)

Additional Product Codes:_____

Review:_____
(Branch Chief) (Branch Code) (Date)

Final Review:_____
(Division Director) (Date)