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

COVER SHEET MEMORANDUM

From: Reviewer Name Jane Doe

Subject: 510(k) Number K180001

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Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).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)