THIRD PARTY "SUBSTANTIAL EQUIVALENCE" (SE)
DECISION MAKING DOCUMENTATION

- 510(k) Holder's Name:
- Primary Third Party Reviewer:

_____ _____
Signature Date

_____
Print Name

- Responsible Third Party Official:

_____ _____
Signature Date

_____
Print Name and Title

Print Third Party Name

	Yes*	No*	
1. Is product a device?			If NO = Stop
2. Is device subject to 510(k)?			If NO = Stop
3. Same indication statement?			If YES = Go To 5
4. Do differences alter the effect or raise new issues of safety or effectiveness?			If YES = Stop **NE**
5. Same technologies characteristics?			If YES = GO To 7
6. Could the new characteristics affect safety or effectiveness?			If YES = Go To 8
7. Descriptive characteristics precise enough?			If NO = Go To 10 If YES = Stop **SE**
8. New types of safety or effectiveness questions?			If YES = Stop **NE**
9. Accepted scientific methods exist?			If NO = Stop **NE**
10. Performance data available?			If NO = Request Data
11. Data demonstrate equivalence?			Final Decision:

*Note: In addition to completing page 2, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation on page 3.