

# **Standards Data Form for Abbreviated 510(k)s**

(Standards Data Sheet)

510(k) Number:

Standard Organization No:

or

Standard Identification No:

or

CDRH Internal Reference No:

Declaration of Conformity Elements:

Any Adaptations Applied	yes	no
Any Requirements Not Applicable	yes	no
Any Deviations Applied	yes	no
Any Differences in Device Tested and Finished Product	yes	no
*Is There a Third Party or Test Lab Involved	yes	no

Was there another standard used in the review of this submission?    yes            no

If another standard was used, please fill out an additional form.

\* This is not the third party that reviews 510ks