

## Advanced Medical Technology Application

This is an application for a **CLAIMS MADE POLICY**. Should this application be accepted by the Company, coverage will apply to claims first made against the insured during the policy period. No coverage will apply for claims first made against the insured after the end of the policy period unless the extended reporting period applies. No coverage will apply for claims first made prior to the retroactive date shown in the declarations page of the policy. **The completion and submission of this application to the Company does not constitute a binder of insurance.** All questions must be answered. If a question is not applicable, please answer "NA". If the answer to a question is none, state "None" or "0". If more space is required to answer a question completely, please provide a separate attachment and identify the question it responds to.

Please check the appropriate block(s)

Products/Completed Operations Liability       Professional Liability

### Applicant Information

<b>1. Applicant:</b>	
<b>2. Address:</b>	
<b>3. Mailing Address:</b>	
<b>4. Locations:</b> <i>(if other than above)</i>	
<b>5. All Named Insureds:</b>	
<b>6. Additional Insureds:</b> <i>(explain relationship)</i>	

**7. If you have acquired any subsidiaries within the last 5 years, identify:**

Entity	Date Acquired

**8. Named Insured is:**

Individual     Partnership     Corporation     Joint Venture     Other *(Describe)*

<b>9. How long has the Named Insured been in business?</b>	
<b>10. Do you have a parent company?</b>	
<b>11. Have you operated under another name?</b> <i>(please give full details)</i>	

<b>12. Projected U.S. revenues?</b>	
<b>13. Projected foreign revenues?</b>	
<b>14. Revenues for current year?</b>	
<b>15. Revenues from previous year?</b>	

**16. Product/Service Profile** (*percentages*)

<b>Source/Potential Source of Revenues</b>	<b>%</b>	<b>Product/Service Description</b>
Medical Devices		
Diagnostics		
Proprietary Bio-Pharmaceuticals		
Generic Bio-Pharmaceuticals		
Contract Research		
Contract Manufacturing		
Distribution		
Equipment Rentals/Leasing		
Repair/Installation/Service		
Other ( <i>please explain</i> )		

**17. Product/Service Breakdown** (*percentages*)

**Contracted Professional Services**

Preclinical Testing		Biostatistics	
Pharmacodynamics		Submission of Regulatory Filings	
Pharmacokinetics		Bioequivalency/Bioavailability Testing	
Protocol Design		Quality Control	
Study Selection or Monitoring		Manufacturing	
Clinical Investigations ( <i>indicate phases</i> )		Repackaging/Assembly	
Clinical Staff Recruitment		Product/Equipment Sterilization	
Clinical Staff Training		Marketing	
Case Report Form Design		Sales	
Data Entry/Database Management		Distribution	
Publications/Software Design		Other ( <i>please explain</i> )	

### Medical Devices

Cardiac		Therapy/rehab	
Anesthesia/respiratory		Dialysis	
Implants - Active		Infusion	
Implants - Non-Active		Non-Cardiac Catheters	
Lasers		Analytical Instruments	
Surgical Devices		Diagnostic Kits	
Dental Instruments		Durable Medical Equipment	
Monitoring		Hospital Products/Supplies	
Imaging Devices		Other ( <i>please explain</i> )	

### Bio-Pharmaceuticals

Vaccines		Imaging/Diagnostic Agents	
Hormones & Steroids		Nutraceuticals	
Injectable/Oral Prescription		Vitamins/Food Supplements	
Topical Prescription		Diet Aids	
Drug Delivery		Other ( <i>please explain</i> )	

<b>18. List new products expected to be introduced:</b>	
<b>19. List any discontinued products:</b> ( <i>Please indicate reason</i> )	
<b>20. Any distributed products manufactured outside U.S.? If yes, is facility FDA approved.</b>	
<b>21. Any product components imported? If yes, are they FDA approved?</b>	
<b>22. Are any products manufactured sold under others' labels?</b>	
<b>23. Are any products sold as components for other products?</b> ( <i>Likely end product</i> )	
<b>24. Do you require Certificates of Insurance from your suppliers? What limits do you require?</b>	
<b>25. Do you contract out product development, manufacturing, sales, distribution services?</b> ( <i>Please indicate activities contracted</i> )	
<b>26. Do any of your products training/certification programs required FDA approval?</b>	
<b>27. Are manufactured products UL listed and/or CSA certified?</b>	

<b>28. Do you use a facility for reliability/design validation?</b>	
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**29. Professional Services**

<b>Do any of your employees provide direct patient care?</b>	
<b>Do they carry their own individual medical malpractice insurance?</b>	
<b>Do you operate an in-patient facility?</b>	
<b>Do any of your employees participate on an Institution Review Board?</b>	
<b>Do you or any of your employees have a financial interest in the products of your clients?</b>	
<b>List largest clients for current year:</b>	

**30. Sponsored Clinical Trials**

<b>Product</b>	<b># Active Subjects Over Next Policy Period</b>	<b>Indications</b>	<b>Country</b>

*\* Please attach FDA approved protocols & informed consent documents for active clinical trials.*

**31. Regulatory**

<b>To the best of your knowledge are you in compliance with FDA Regulations or foreign agency equivalent?</b>	
<b>Any product recalls in the past year?</b> <i>(If yes, please submit details &amp; recall status)</i>	
<b>Within past 12 months, has there been any MDR's or AER's filed?</b> <i>(if yes, indicate the number of filings and the nature of each)</i>	
<b>Date &amp; result of most recent FDA inspection.</b> <i>(please submit a copy of Form 483 and your documented response)</i>	
<b>Have any products or company practices been subject to an investigation by any government agency?</b> <i>(If yes, please explain)</i>	
<b>Any clinical trials placed on a clinical hold?</b> <i>(if yes, provide details)</i>	
<b>Do you audit Clinical Investigator performance?</b>	
<b>Any warning letters issued against you in the last 3</b>	

years? (if yes, please explain)	
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**32. Risk Management**

<b>Loss Prevention/Control Program?</b> <i>(if yes please name person in charge of program)</i>	
<b>Written Quality Control Program?</b>	
<b>Written Product Recall Plan?</b>	
<b>Written Records Retention Program?</b>	
<b>Promotional materials, contracts, guarantees, &amp; labeling jointly reviewed by each applicable discipline?</b>	
<b>Other</b> <i>(please explain)</i>	

**33. Loss History**

*\*Total aggregate cost (losses from ground up including defense) for last five years*

<b>Policy Period</b>	<b>Insurer</b>	<b># of Claims</b>	<b>Total Incurred</b>

*\*Attach previous carrier loss runs*

<b>Describe all incurred losses of \$10,000 or more:</b>	
<b>Any known occurrence(s) not yet reported?</b> <i>(If yes, please submit details)</i>	

**34. Coverage History**

<b>Policy Period</b>	<b>Primary &amp; Excess Limits</b>	<b>Carriers</b>	<b>Retro Date</b>

<b>Has your insurance ever been canceled or non-renewed by a carrier?</b> <i>(if yes, please explain)</i>	
<b>What limit of liability are you seeking?</b>	

<b>What Deductible or SIR are you prepared to carry?</b> <i>(Please indicate which type)</i>	
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*\*When requesting excess coverage please provide underlying premium figures and policy terms & conditions.*

**35. Please include the following with this application:**

- Most recent Annual Report/Audited Financial Statement or most recent 10K & 10Q.
- Clinical trial protocols & informed consent documents
- Senior staff curriculum vitae
- Outline of Quality Control Program
- Advertisements, brochures, descriptive literature
- Sample service contracts & indemnification agreements

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Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties, including but not limited to fines, denial of insurance benefits, civil damages, criminal prosecution and confinement in state prison.

**Applicable in Colorado**

Any insurance company or agent of an insurance company who knowingly provides false, incomplete, or misleading facts or information to a policyholder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado division of insurance within the department of regulatory agencies.

**Applicable in California**

For your protection California law requires the following to appear on this form: Any person who knowingly presents a false or fraudulent claim for the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison.

Completing and signing this application does not bind coverage. Coverage will not be bound, nor will a policy be issued until the applicant signifies acceptance of the Company's premium quotation.

The undersigned **authorized officer of the applicant** knows of no other relevant facts which might affect the Company's judgment when considering this renewal application and warrants that the statements herein are true, and it is agreed that this renewal application shall be the basis of the renewal contract and shall be deemed incorporated therein should the Company evidence its acceptance of this renewal application by issuance of a renewal policy. It is agreed that this renewal application shall be on file with the Company and that it shall be deemed to be attached to and made part of the renewal policy, if issued, as if physically attached to the renewal policy.

Signature: \_\_\_\_\_ Title: \_\_\_\_\_

Print Name: \_\_\_\_\_ Date: \_\_\_\_\_